VOL. 12 NUMBER 1

Food-Drug-Cosmetic Law Journal

MARCH • 1957

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A. R. MILLER

Compulsory Iodization of Table Salt . .
L. M. McBRIDE, FRANK J. MADDEN,
LOUIS H. HALL, JR.,
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COMMERCE CLEARING HOUSE PUBLICATION

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. On this basis, contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $15 per year, including a handsome binder to hold one year's issues. Single copies are $1.50 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 30, Ill. Printed in United States of America.

March, 1957
Volume 12 • Number 3

Entered as second-class matter December 30, 1948, at the Post Office at Chicago, Illinois, under the Act of March 3, 1879.

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REPORTS

TO THE READER

About the Authors

A. R. Miller is Chief of the Meat Inspection Branch of the Agricultural Research Service, United States Department of Agriculture, at Washington, D. C. Dr. Miller's contribution to this March JOURNAL is adapted from a speech which he delivered at the twelfth annual meeting of the Section on Food, Drug and Cosmetic Law, New York State Bar Association, on January 23, 1957, in New York City.

According to the writers of our second article, "certain members of the medical profession and public-health groups endeavored in 1947 to have federal legislation [the Bolton bill] passed which, in substance, would force all salt for human consumption to be iodized as a condition to its introduction into interstate commerce." The bill met with severe opposition, dying in committee. Anticipating the possibility of the introduction of another such bill during the current session of Congress, the Salt Producers Association appointed a committee, consisting of four lawyers, to prepare a brief in support of the opposition on legal grounds (the basis of opposition is legal rather than factual).

The brief is designed for presentation to the subcommittee of the Interstate Commerce Commission, if necessary, and it has been edited into article form for publication in the JOURNAL.

The committee—L. M. McBride, Frank J. Madden, Louis H. Hall, Jr., and Vincent I. Compagno—is, in the words of Mr. McBride, "genuinely soliciting helpful legal comments which may come from the field."

L. M. McBride heads the law firm of McBride & Baker, general counsel for Morton Salt Company. Mr. Madden, in addition to being a lawyer, is full-time managing director of the Salt Producers Association. Mr. Hall is a partner in the firm of Putney, Twombly, Hall & Skidmore, of New York City, general counsel for International Salt Company. Mr. Compagno is a partner in the firm of Chickering & Gregory, of San Francisco, general counsel for Leslie Salt Company.

L. M. Beacham, Assistant Chief of the Division of Food, Bureau of Biological and Physical Sciences, Food and Drug Administration, joined the Administration in 1934 as an inspector of canned shrimp in the Supervisory Inspection Service. Two years later, he became a chemist in the Canned Foods Branch of FDA's Food Division. Since 1941, he has held important administrative positions in the Washington offices. Mr. Beacham, a graduate of the University of South Carolina, did graduate work at Rutgers University.

Eugene H. Holeman is superintendent and state chemist in the division of food and drugs of the Tennessee Department of Agriculture, at Nashville.

An interesting, practical study is presented in **Leonard J. Robbins'** "The American Pharmaceutical Manufacturer and Foreign Patents—Present Problems and Future Trends." Mr. Robbins is associated with Langner, Parry, Card & Langner, of New York City.

Statement, Food Protection Committee, Food and Nutrition Board

"STATEMENT ON WHAT WE KNOW ABOUT POSSIBLE RELATIONSHIPS BETWEEN CANCER AND FOOD ADDITIVES

"DECEMBER 1956

"In the development of our knowledge of nutrition, primary emphasis has been given to deficiencies that may occur in our diets and to ways of safeguarding against them. Along with the application of such knowledge a notable reduction in dietary deficiency diseases has occurred. With decreasing need in the United States for emphasis in this direction, more effort has been devoted to the investigation of positive factors in foodstuffs that might be detrimental to health.

"A group of conditions broadly termed 'degenerative diseases' has assumed major importance as causes of illness and death in recent decades. The causes of these conditions are under intensive investigation, and especial emphasis is being placed on the role of environmental factors.

"Causal relationships between environmental factors and human disease have long interested scientists. Indeed, knowledge of such relationships underlies most advances in preventive medicine. It is not surprising, therefore, that investigators at present are trying to determine whether factors in the environment are causally related to the occurrence of cancer in man. As has been true in the study of all diseases whose causes are unknown, the elements of the environment to which man is constantly or repeatedly exposed, e. g., the atmosphere, water, and foodstuffs, command the greatest share of attention.

"Legitimate conjecture

"Conjecture concerning possible cause and effect relationships is a common and sometimes an effective device in the development of new knowledge concerning disease. Many discussions concerning the possible relation of chemicals which may occur in foods to the occurrence of cancer in man have been held at scientific meetings and reports of these have recently appeared in scientific publications. Scientists involved in discussions of food additives and cancer recognize the *conjectures* as such, and ascribe importance to them only insofar as they may stimulate the kind of inquiries which will help advance knowledge. When the scientific discussions, either written or spoken, have been reported through the press and other news media for public information, however, the conjectural nature of the scientists' discussions has frequently been forgotten, misconstrued, or poorly stated. This has contributed to the present apprehension among consumers over the safety of the food supply, and to the concern among food manufacturers over the possible loss of consumer confidence.

"In view of these circumstances, it is desirable that a statement be made clarifying for the public the present state of knowledge about the relation between food additives and occurrence of cancer in man.

"Known facts

"What is ***known*** concerning a definite relationship between ingestion of a substance and the subsequent development of cancer in man? Accidental repeated ingestion of 'radium paint' or the use of so-called 'radium water' has been followed by the development of cancer of the bone. The ingestion of certain aromatic amines, such as b-naphthylamine or 4-aminodiphenyl, through industrial exposure has been associated with the occurrence of cancer of the the bladder. Epidemiologic evidence indicates that a prolonged intake of sufficient arsenic may result in development of cancer of the skin.

(Continued on page 192)

WASHINGTON–

ACTION AND NEWS

In the Food and Drug Administration

Monthly Report, Issued February 25, 1957.—Voluntary destruction, by owners, of 2,935 tons of foods damaged in recent disasters was reported by the Food and Drug Administration on February 25. The Administration maintains surveillance over such products during salvage operations to prevent dangerously contaminated items from reaching the public.

Approximately 2,700 tons were canned citrus juice in the hold of a freighter when it was rammed by a tanker near the entrance of New York harbor last July. The ship rolled over near the port of Brooklyn and polluted harbor water covered the cargo. When the cans of juice were brought up by cranes and loaded on scows, they were covered with mud and fuel oil, and most of the labels were gone. Rust, pinholes and swelling began to develop. It was agreed that the merchandise was unfit for consumption. The cans were removed to a junk yard where they were pressed into bales of scrap metal.

Administration surveillance was also required following an explosion at a Brooklyn pier in December. About 27 large food-manufacturing and warehousing firms had stocks in the area. Damage resulted from polluted harbor water used to keep down the fires and from excessive heat and flying debris, including glass splinters.

Working with the city health department, FDA inspectors checked the damaged merchandise and supervised destruction of approximately 235 tons of food that might injure consumers. Candy, chewing gum, coffee, tea, rice and miscellaneous warehoused items were included.

Fifty federal court seizures in January removed 266 tons of unfit food from the market. More than half of the volume consisted of bulk wheat and barley containing seed grain treated with a poisonous mercury compound. Six other seizures involved watered oysters.

In the same period, seven lots of drugs and "health foods" were seized —three for false and misleading curative claims and four for faulty composition. One of the misbranded products, according to FDA, was honey, but the label claimed:

"It strengthens the heart, the liver, the pancreas, and all vital organs of the human system. A Spoonful A Day Keeps The Doctor Away."

Another was a vitamin and mineral formula. The promoter claimed that it was a cure for poliomyelitis, cancer and tuberculosis.

More About Radioactivity Survey—Canned Foods in Antarctica.—Canned foods left in Antarctica by the Scott and Shackleton Expeditions more than 40 years ago will help the Food and Drug Administration to establish basic scientific data on the natural radioactivity of food.

John L. Harvey, Deputy Commissioner of Food and Drugs, has announced that samples of the canned foods left in the Antarctic "deep freeze" were being made available to FDA scientists through the cooperation of the United States Antarctic Programs and the British and New Zealand Governments.

The late Admiral Richard E. Byrd, officer in charge of United States Antarctic programs, said:

"It is significant that efforts of early Antarctic explorers are still yielding scientific data of importance to world health in our own times."

The foods will be obtained from the camp site at Cape Royds, built and occupied by the British Antarctic Expedition of 1908-1909, under Sir Ernest Shackleton, and the camp at Cape Evans established by Captain Robert Falcon Scott, of the Royal Navy, during his last Antarctic expedition from 1910 to 1913.

Both sites were designated as shrines, early in 1956, by Admiral George Dufek, Commander of United States Task Force 43, now in Antarctica. Extensive stores of foods remain at both camps, with the cans packed in sawdust in the original cases, according to Captain Richard Black, USNR, who visited the locations in 1956. He said most of the foods appeared to be in "perfect condition." Samples of powdered milk have already been obtained from Little America Camp No. 3, established by Admiral Byrd in 1940.

The samples from the Scott and Shackleton camps will be collected by Captain E. E. Hedblom (MC) USN, and Dr. J. Findley, of Pahiatua, New Zealand, medical officer at New Zealand's Scott Base on McMurdo Sound. Duplicate samples will be supplied for study by British scientists.

Mr. Harvey said that FDA will use the Antarctic specimens to complete its collection of authentic samples of canned foods packed prior to 1945—"year one" of the atomic age. These foods will provide base measurements for a continuous survey of the radioactivity of common foods begun by FDA. Mr. Harvey pointed out that there is no significant radioactivity in the United States food supply today. "This is only a scientific study which will help us to evaluate any future increase in radioactivity, should that become necessary. The results of the study will be made available for publication," he said.

In the Public Health Service

Report on Polio Vaccine.—On March 1, Dr. Leroy E. Burney, Surgeon General of the Public Health Service, reported a notable increase in demand for poliomyelitis vaccine. According to the vaccine producers, over 4 million doses of vaccine were shipped during the week ending February 15—the highest amount ever shipped in a single week.

Last fall, vaccinations dropped off and supplies of vaccine began to pile up on shelves of manufacturers. Demand began to pick up early in January. During that month, 11 million doses were shipped, as compared with only 5 million in December, 1956. At the time of Dr. Burney's report, the backlog of unshipped vaccine was less than 15 million cc.

Vol. 12, No. 3 March, 1957

Food·Drug·Cosmetic Law
Journal

Federal Meat-Inspection Law

By A. R. MILLER

The Chief, Meat Inspection Branch, Department of Agriculture, Discussed Classification of Foods as to Their Being Subject to the 1906 Inspection Act, in His January 23 Address to the New York State Bar Association's Section on Food, Drug and Cosmetic Law

THE INSPECTION PROGRAM organized under the Federal Meat Inspection Act of 1906 has developed down through the years in size, scope of coverage, and complexity. As an inspection program, it has been obliged to keep abreast of progressive changes in our national economy and, more particularly, those progressive changes that have occurred in a large and enterprising industry.

The meat-packing industry subjected to the inspection control required by the statute has always been one of the largest commercial enterprises in this country. Its operations and merchandising practices are characterized by aggressive application of all modern concepts of sales, engineering and research skills. Large, highly competitive, nationally known industrial institutions have grown up in the industry. Competing successfully with these large institutions are many medium-sized and comparatively small meat packers, all of whom operate under the same inspection controls if engaged in interstate commerce. These controls are applied to a tremendous range of production facilities and a great variety of processed meat food products.

The past few years have been marked by a dramatic extension of the federal meat-inspection program both in plants and products.

This expansion includes a large number of meat packers who heretofore have not been subject to the federal meat-inspection law because their business did not extend to interstate commerce. It includes many new meat food products which have been developed during these years to attract the consumer's dollar. These newly inspected establishments and new products have presented interesting problems for the inspection program. We consider it significant that the law of 1906 and the inspection program organized under that law have proved to be adequate to handle these problems.

Importance of Food Classification

The subject that I have chosen to develop more specifically here today is concerned with classification of foods as to whether they are subject to the terms of the Federal Meat Inspection Act. Of course, this question arises only if the food is to be shipped interstate and if the food is prepared in whole or in part from products derived from cattle, swine, sheep, goats or horses.

This classification is of utmost importance to the manufacturer and shipper. The manufacturer must meet the inspection requirements in order that the products of his plant may be inspected and identified as such. As for the shipper, if the food is subject to the Meat Inspection Act, it must have been inspected and identified as such to be lawfully moved interstate.

Requirements of Inspection Supervision

Inspection requirements apply to the plant facilities, including both structural and equipment details. To qualify for the mark of inspection, the meat must have been derived from healthy animals and normal carcasses. It is required that the live animals be inspected to eliminate all that are unfit. Each carcass at the time of slaughter must be inspected to eliminate any carcass or part of carcass which is unfit for food. No slaughtering or other processing may be conducted in the inspected meat-packing plant except under inspection supervision. This inspection supervision extends not only to the slaughtering department, but to all manufacturing processes, such as curing, smoking, canning and sausage manufacture. Standards of composition are prescribed and enforced with respect to all classes of inspected meat food products to assure against adulteration and to assure compliance with consumer expectancy. Finally, only those

labels may be used which have been approved for the particular product and which have been reviewed to assure against the presence of any misleading feature.

You can see that the manufacturer has a real interest in knowing whether his food is subject to the federal meat-inspection law and its inspection requirements.

The law requires that inspection controls apply to certain food animals and their carcasses and it also states that they apply to meat food products prepared from such carcasses. It was apparent from the start that the rule-making power given the Secretary of Agriculture in the Meat Inspection Act would have to be used in deciding just which foods are to be classed as meat food products subject to the inspection. It is apparent that many classes of foods containing ingredients derived from the carcasses of food animals should not be brought under the law. Shortenings containing fats derived from food animals are widely used in many products in the baking industry. While such shortenings are subject to the inspection, the law has not been regarded as applying to bakery products such as bread, cakes, crackers and cookies.

Bakery-Products Rule—Application to Other Classes of Foods

The rule that was applied in the case of bakery products has been used in classifying other products that are primarily prepared by industries other than the meat-packing industry. These have included fishery products, dairy products and poultry products.

This does not mean that a meat food containing a dairy product, for example, may not be classed as a meat food product subject to the law. In fact, most products of the dairy industry are used as ingredients of some of the many meat food products prepared by the meat-packing industry. For instance, nonfat dry milk is commonly used in limited amounts in certain sausage products. Cheese is used as a minor ingredient of many so-called specialty items.

Cheese spreads containing small amounts of bacon or ham have been classed as being primarily dairy products that are not subject to the meat-inspection law. On the other hand, spreads prepared principally with bacon or ham and containing small amounts of cheese have been classed as being subject to the law. Such products are prepared principally by the meat-packing industry.

The classification of chicken soup prepared with beef broth proved to be an interesting experience and helped to clarify one of the principles that applies to the classification problem. For many years this product was classed as being subject to the meat-inspection law because of the beef-broth ingredient. Chicken products, of course, are primarily the interest of the Food and Drug Administration, which has worked out policies and standards that apply to chicken products as a class. Our application of the meat-inspection law to chicken soup with beef broth brought the meat-inspection program into a class of foods covered by the Food and Drug Administration. We reviewed our position with respect to that product and decided that the inspection requirement would not be applied to chicken soup with beef broth. This decision gave recognition to a principle that the meat-inspection law would not be applied to an item which logically comes within a class of foods for which the Food and Drug Administration develops standards and policies.

Meat-Inspection Law and Dehydrated Soups

This principle turned out to be very useful in deciding on the classification of the many kinds of so-called dehydrated soups which have been placed on the market in recent years. We early took the position that the meat-inspection law would not be applied to dehydrated soups.

Pâté de foie gras is another poultry product which sometimes contains a small amount of meat product. Sometimes the goose livers are packed in lard. For years this was classed as a meat food product because of the lard content. However, some time ago it was decided that since *pâté de foie gras* is primarily a poultry product, the Food and Drug Administration should be enabled to apply its policies and standards to this item along with all other poultry products that come under its control.

We are frequently asked to consider the probability of classifying foods according to the percentage amount of meat ingredient. This approach certainly has simplicity to recommend it, if workable. We have many times studied the practicality of using the percentage formula, but each time we have been forced to realize that the results of applying such a formula would be quite unrealistic. To apply the inspection requirements of the law to only those products containing a certain amount of meat would either remove the inspection control

from many recognized meat food products prepared by the meat-packing industry or extend the inspection requirements to many foods that are recognized as being the products of other industries. The results would be either too restrictive or too inclusive, depending on the percentage used in determining the classification.

The policy presently followed in deciding whether a food is subject to the inspection requirements of the federal law is not easy to apply. When applied with full information concerning the food to be classified, the results are practical and realistic. It applies the law to the industry that was the subject of Congressional inquiry when the law was enacted. The policy also carves out, realistically, areas of control for the two federal agencies, namely, the federal Food and Drug Administration and the federal Meat Inspection Service.

Spaghetti products served to test the effectiveness of the classification system. It is possible to identify two classes of spaghetti products: the one clearly not a meat food product and, therefore, subject to the Food and Drug Administration control and the other recognized as a meat food product subject to the inspection control. Those that are identified as being meat food products are "spaghetti with meat" and "spaghetti with meat balls." Each of these is required to be prepared under inspection. Not only must these products be prepared in a plant that has qualified for the inspection and their preparation be supervised by the inspection program, but they must contain at least the amount of meat prescribed for these products by rules promulgated by the Secretary of Agriculture.

Name Identification of Meat Food Products

These products illustrate another principle which is applied in classifying foods. Their names identify them as being meat food products. This is important because a processor cannot remove "spaghetti with meat balls," for example, from the application of the inspection law merely by reducing the amount of meat in the product below the prescribed standard. He is told that "spaghetti with meat balls" is classed as a meat food product required to be prepared under inspection and which must contain at least the prescribed amount of meat.

Soups have presented a similar situation. Most of them are obviously not subject to the meat-inspection requirement. Those soups that are identified as being meat food products are covered

by the meat-inspection law. These include "vegetable beef soup," "beef bouillon," "bean and frankfurter soup," "bean and bacon soup," and the like. Soups so identified, in addition to meeting all of the inspection requirements, are subject to composition requirements which prescribe minimum meat content below which these products are not permitted to fall.

Traditionally, such products as sandwiches, mincemeat and "pork and beans" have not been classed as meat food products, each for a somewhat different reason. Sandwiches would present an impossible control problem. Mincemeat, in fact, has never contained meat. "Pork and beans" should be called "beans and pork" for it has always been a product containing only an infinitesimal amount of pork fat.

In recent years, many new foods have been developed and merchandised. Many of them are prepared with varying amounts of meat. These latter products have presented many interesting problems of classification. In each case the manufacturer has a considerable amount at stake. His enterprise is very significantly affected by the decision as to whether his food is a meat food product subject to the inspection control. In each case the classification of the food is made objectively with full regard for what have come to be recognized as established principles.

Refined and Deodorized White Grease—Its Status

Another kind of classification problem is illustrated by decisions that white grease which has been refined and deodorized to the point where it resembles an edible rendered animal fat is subject to the meat-inspection law. White grease is the inedible product rendered from condemned and inedible tissues derived from hog carcasses. These tissues are rendered in the so-called inedible tankhouse. There is quite an accumulation of these inedible tissues in the trade. They are derived from hogs that have died in transit, sick animals that are condemned on ante-mortem inspection and taken directly to the inedible tankhouse, hog carcasses and parts of carcasses condemned at the time of post-mortem inspection, floor sweepings, and refuse hog fat and tissue of many kinds and from many sources. Refining and deodorizing devices have been perfected to the point where the fat rendered from these low-grade materials can be given the appearance, odor and taste of an edible rendered fat. This product has been classed as being subject to the terms of the meat-inspection law. The

terms of the law prohibit the application of the mark of inspection to rendered fats other than those that are derived from clean, edible tissues that have passed the inspection. This article, which resembles an edible product but which in fact is not eligible for the marks of inspection, cannot be shipped in interstate or foreign commerce in compliance with the law. A case involving this point was decided by the Supreme Court in 1918 in *Pittsburgh Melting Company v. Totten*, 248 U. S. 1. The court held that such an inedible rendered fat which resembles an article fit for human consumption is debarred from interstate and foreign commerce. However, the Court held that such fat might be denatured to make it unavailable for human consumption and remove it from the operation of the Meat Inspection Act.

The power of the Secretary to classify meat food products under the meat-inspection law was tested early in the courts. Three cases—one decided in 1915 by the Circuit Court of Appeals for the Third Circuit and two decided by the Supreme Court in 1918—upheld the Secretary in action taken by him with respect to representative meat food products.

Importance of Uniform, Realistic Decisions

The decision that a food containing a meat ingredient is subject to the meat-inspection law may be of considerable significance to a manufacturer. The planning, manufacturing and distribution of the food that is subject to the inspection law involves a considerable amount in the way of plant facilities, inspection requirements and composition controls. We recognize the importance, therefore, that these decisions be applied uniformly and realistically. A new food is classed as being subject to the inspection requirement only after thorough study of all of the circumstances and a careful application of established principles. **[The End]**

• VETERANS ADMINISTRATION TESTS TB DRUG •

A new antibiotic—streptovaricin—will be tested against tuberculosis in the Veterans Administration's internationally known TB chemotherapy program, the administration announced on March 20. The study is beginning in ten hospitals, located in the following cities: the Bronx, New York City; Manhattan, New York City; Castle Point, New York; Coral Gables, Florida; East Orange, New Jersey; Long Beach, California; Memphis, Tennessee; Minneapolis, Minnesota; New Orleans, Louisiana; and Wood, Wisconsin.

About 100 patients will be treated for eight months with a combination of streptovaricin and isoniazid, a commonly used TB drug.

COMPULSORY IODIZATION OF TABLE SALT

THE PREVALENCE of endemic goiter in the so-called goiter belt centering in the State of Michigan caused certain segments of the medical profession to focus their attention on the iodization of salt for human consumption as a means of reducing the high incidence of goiter in that area. From the resulting agitation there emerged a program of collaboration between Michigan health authorities and the salt industry, with the latter as early as 1915 making table salt available in both plain and iodized forms. This practice on the part of the industry has prevailed ever since, so that on a national marketing basis the consumer has had his choice of plain table salt or iodized table salt.

Notwithstanding, certain members of the medical profession and public-health groups endeavored in 1947 to have federal legislation passed which, in substance, would force all salt for human consumption to be iodized as a condition to its introduction into interstate commerce. This proposed legislation was known as the Bolton bill.[1] It met with severe opposition and finally died in committee, but agitation for its revival has persisted and current efforts in that regard are becoming somewhat more vocal.

The opposition of the Salt Producers Association is not predicated on medical grounds. The propriety of iodized salt as an agent for the prevention of endemic goiter is left for the medical profession. Nor does the association protest such legislation because of any resulting

[1] H. R. 2717. It provided as follows:

"Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That paragraph (a) of section 301 of the Federal Food, Drug and Cosmetic Act, as amended (U. S. C., 1940 edition, title 21, sec. 331), is hereby amended by inserting '(1)' after 'interstate commerce' and by striking out the period at the end of such paragraph and inserting a comma and the following: 'or (2) of salt (sodium chloride) sold or to be sold for table use, unless it contains suitable iodides in a quantity equivalent to not less than 80 parts and not more than one hundred and sixty parts of iodine per million parts of such salt'.

"Sec. 2. The amendment made by this Act shall take effect on the thirtieth day after the date of the enactment of this Act."

By L. M. McBRIDE, FRANK J. MADDEN,
LOUIS H. HALL, JR., and VINCENT I. COMPAGNO

This Study's Content Is Drawn from a Brief Prepared for the Salt Producers Association by the Writers—a Committee of Four Lawyers—in Anticipation of the Possibility of Another "Bolton Bill"

production or marketing problems. The opposition is based entirely on legal concepts. Such legislation is regarded, first, as an unprecedented, unnecessary and undesirable extension of governmental control over private enterprise and, second, as a violation of due process.

Regulatory Objections

Congressional intent as to the proper scope, purposes and objectives of legislation excluding articles from interstate commerce has thus far been clear and consistent. The consistency of such intent can best be measured by a careful analysis of legislative results from 1884 to date. In 1884, Congress first exercised its broad power to exclude articles from interstate commerce by enacting legislation prohibiting the exportation or shipment in interstate commerce of diseased livestock.[2] Since that time, Congress from time to time has enacted legislation prohibiting the shipment in interstate commerce of moths, plant lice, insect pests,[3] diseased nursery stock,[4] lottery tickets,[5] liquor,[6] game birds,[7] convict-made goods,[8] stolen motor vehicles,[9] kidnapped persons,[10] stolen property,[11] prize-fight films,[12] women for immoral pur-

[2] 23 Stat. 31 (1884), 21 USCA Sec. 119 (1927).
[3] 33 Stat. 1269 (1905), 7 USCA Sec. 141 (1952).
[4] 37 Stat. 315 (1912); 46 Stat. 103 (1928).
[5] 28 Stat. 963 (1895), 18 USCA Secs. 1301-1305 (1950).
[6] 37 Stat. 699 (1913), 27 USCA Sec. 122 (1955).
[7] 31 Stat. 188 (1900), 18 USCA Sec. 43 (1950).
[8] 45 Stat. 1084 (1929), 49 USCA Sec. 60 (1951).
[9] 41 Stat. 324 (1919), 18 USCA Sec. 312 (1951).
[10] 47 Stat. 326 (1932), 18 USCA Sec. 1201 (1950).
[11] 48 Stat. 794 (1934), 18 USCA Sec. 2314 (1951).
[12] 54 Stat. 686 (1940), 15 USCA 1001 (1948).

poses,[13] adulterated and misbranded products,[14] deceptive and deleterious filled-milk products [15] and commodities produced under substandard labor conditions.[16]

From a determination and consideration of the scope, purpose and objectives of legislation excluding the above articles from interstate commerce, a most significant fact becomes apparent. In each instance, the legislation was designed to protect the public from harmful or deceptive commodities, to support certain local policies of the states in the exercise of their reserved powers, to prevent the use of interstate commerce to promote immorality or dishonesty, or to prevent the use of interstate commerce as the agency for the spreading of evil or harm or for the distribution of goods produced under substandard labor conditions. These are the basic objectives and purposes of all legislation by which Congress has excluded articles from interstate commerce from 1884 to date. Congressional intent as to the proper basis and necessity for excluding articles from interstate commerce, when measured by such purposes and objectives, is clear and consistent. It is evident that Congress has determined that such legislation should be designed to protect the public from a substantial harm or evil and the commodity excluded from interstate commerce must be harmful of itself or have a direct and substantial relationship to the condition sought to be controlled or eliminated.

An even more significant fact emerges from an analysis of the scope, purposes, objectives and effects of such legislation: *There is no legislative or regulatory precedent for excluding harmless products from interstate commerce as a means of compelling a private manufacturer to add medicaments to such products,* yet it is apparent that the enactment of the proposed legislation would seek to do precisely that. It is this heretofore unknown concept of commerce regulation which is urged as an unnecessary and undesirable extension of governmental control over private enterprise.

The condition necessitating the enactment of such legislation, according to its proponents, is that of simple or endemic goiter and the health problem of seeing to it that people in low-iodine areas receive a quantity of iodine which the medical profession considers to be a daily minimum requirement. Implicit in the position of the proponents

[13] 36 Stat. 825 (1910), 18 USCA Sec. 2421 (1951).
[14] 34 Stat. 768 (1906), 21 USCA Sec. 301 (1938).
[15] 42 Stat. 1487 (1923), 21 USCA Sec. 62 (1955).
[16] 52 Stat. 1068 (1938), 29 USCA Sec. 265 (1955).

is the assumption that the compulsory iodization of all salt produced for human consumption is the only way in which endemic goiter can be effectively prevented, controlled or eliminated. The facts do not support this assumption. This becomes apparent upon a consideration of the history of endemic goiter in the United States, the universal availability of iodized salt in the United States and the results of various *voluntary* programs in the United States and Mexico directed toward the prevention of endemic goiter.

In response to urgings of the medical profession, the salt industry began to iodize table salt as early as 1915. This was done voluntarily as a public service. In each year since 1915 the salt industry has iodized a substantial portion of all salt produced and sold for table purposes. Additionally, the areas of distribution have been such that iodized salt has been continuously available to the public in every section of the country for well over 15 years. In 1924, the prevention of endemic goiter by the general use of iodized salt was the basic objective of a program undertaken in the State of Michigan. The program was started by obtaining the cooperation of salt producers, wholesale grocers and the state department of health. The department of health gave all instructions and advice so that there was no advertisement or comment by the salt industry. In 1923 and 1924, a survey was made in four counties of the State of Michigan to determine the incidence of goiter among school children. The four counties selected were chosen because they were equidistant, on a diagonal line, from Lake Superior to the north and from Lake Erie to the south. The percentage of goiter in the schools of these four counties was taken as the basis for calculating the goiter incidence throughout the State of Michigan. Follow-up surveys of the same four counties were also made in 1936 and 1951. The results of these surveys were striking. The incidence of goiter in Michigan was 38.6 per cent in 1924, 9 per cent in 1936 and 1.4 per cent in 1951. The conclusion is self-evident. The problem of endemic goiter in a low-iodine area had been solved by a voluntary program.

Moreover, other voluntary programs and experiments for the prevention of goiter have established that products or elements other than salt can be used to administer iodine to persons in any group having a high incidence of goiter. One of the first of such experiments was made in the schools of Akron, Ohio.[17] The experiment was started

[17] O. P. Kimball, M. D., "History of the Prevention of Endemic Goiter," 9 *Bulletin of The World Health Organization* 241 (1953).

late in 1916 and carried out over the next four years. Approximately 5,000 girls underwent preventive treatment. Three grains of sodium iodide were added to their drinking water for a period of ten days in the spring and ten days in the autumn. This method of preventive treatment was very effective. Of the girls who originally had thyroid enlargement, two thirds were diagnosed as normal on later examination after completion of the experiment.

In 1951 and 1952, a similar experiment was made in the Federal District of Mexico among 15,000 school children in 45 different schools.[18] Resistance developed to the taking of sodium iodide in drinking water, the children complaining about drinking the iodized solution and the teachers complaining about the amount of time taken to carry out the experiment. To overcome these difficulties, candy was used as the vehicle for iodine. The candy was made of sucrose and glucose at a cost of one cent per piece and contained about ten milligrams of potassium iodide. This method was satisfactory to teachers and pupils and, according to a survey carried out in five of the schools, the incidence of goiter among school children in the federal district dropped about 16 per cent as a result of the preventive treatment.

In addition to the demonstrable fact that endemic goiter can be effectively prevented, eliminated and controlled by voluntary programs and by the use of products other than salt as vehicles for iodine, it should be observed that the cause or causes of endemic goiter have not been established by medical science. Endemic goiter has been known to medical science for well over 100 years and, during that time, has been the subject of investigations in Europe, South America, Asia, Central America and North America. Such investigations have been designed, in part at least, to obtain evidence as to the causes of endemic goiter. The conclusions drawn as to the cause or causes of endemic goiter by some of the most renowned experts in the field on the basis of these investigations are most revealing.

In 1863, Verchow concluded that the first phase in the production of simple goiter could be brought about *either* by a low iodine intake *or* by the presence of goitrogenic substances in the diet or drinking water.[19] Subsequently, Marine and Lenhart championed the school that emphasized the importance of an inadequate iodine level in the

[18] H. H. Stacpoole, M. D., "Prophylaxis of Endemic Goiter in Mexico," 9 *Bulletin of The World Health Organization* 283 (1953).

[19] R. Verchow (1863-1867), *Die Krankhaften Geschwulste* (Berlin), Vol. 3, p. 4.

production of goiter [20] and McCarrison in 1928 championed the role of the goitrogens.[21] In 1953, Selwyn Taylor, a surgeon and lecturer in surgery at the Post-graduate Medical School of London, England, pointed out that the causation of goiter was still largely unexplained [22] and concluded that *either* a low intake of iodine *or* the presence of goitrogenic substances in the diet or drinking water might be responsible. The more likely cause of goiter, according to Dr. Taylor, is some inherent fault in an individual's thyroid gland by reason of which it is incapable of functioning properly while receiving amounts of iodide apparently adequate for the rest of the population.

Thinking, with respect to the necessity for endemic-goiter legislation, has been confused. The significance of the fact that there is no relationship whatsoever between uniodized salt and endemic goiter is not always recognized. Additionally, many have lost sight of other essential facts regarding uniodized salt, the product slated for exclusion from interstate commerce under the proposed legislation, and of the dangers latent in legislation of this type. Although obvious, the fact that there is no health hazard, deception or evil attendant on the sale or consumption of uniodized salt should be noted. Federal and state laws and regulations require salt products designed for human consumption to be sold only under labels carrying full disclosures as to contents, and all salt produced for table and kitchen purposes is packaged under such labels. Additionally, with respect to all such salt, labels on all packages containing iodized salt exhibit the unmistakable and readily apparent designation "iodized." Moreover, for years the fact that both iodized and uniodized salts were produced and available for table and kitchen purposes has been extensively advertised by the salt industry and known by the average consumer.

The unescapable conclusion, then, is that even if endemic goiter were a health problem in the United States as a whole—as it was in certain areas of Michigan, Ohio and West Virginia in the 1920's and early 1930's—it would be a problem which could be and would be effectively and easily eliminated and controlled by voluntary programs. Iodized salt has been, and will continue to be, universally available in the United States for use in carrying out any such programs. The

[20] D. Marine and C. H. Lenhart (1910), 12 *Journal of Experimental Medicine* 1311.

[21] R. McCarrison (1928), in *Comptes rendus de la conference internationale du goitre, Berne*, (August 24-26, 1927, Berne), p. 303; (1935), in *Zweite internationale Kropfkonferenz* in *Bern* (August 10-12, 1933). *Verhandlungs Bericht ..... Bern*, p. 354.

[22] Selwyn Taylor, "An Autoradiographic Study of Simple Goiter," 9 *Bulletin of The World Health Organization* 197 (1953).

control and elimination of an endemic-goiter problem in four counties in Michigan, in two cities in Ohio, in West Virginia or in Sauk Center, Wisconsin, although socially desirable, does not warrant the exclusion from interstate commerce of uniodized salt. Additionally, direct control and measurement of the daily iodine consumption of any person having endemic goiter cannot be obtained merely by excluding uniodized salt from the market place. Such control would appear to be very important on the individual level. Moreover, if goitrogenic substances or a defective thyroid gland cause endemic goiter, compulsory iodization could not effectively accomplish the primary objective of the proposed legislation.

The danger to free enterprise which is latent in legislation of this type is clear. It would be a precedent for the exclusion of harmless, nondeceptive products from interstate commerce for any purpose whatsoever, for the exclusion of such products from interstate commerce even though they in no way cause or contribute to the condition sought to be controlled or eliminated, and for the compulsory addition of antibiotics to soups, fluorides to toothpaste, vitamins to milk, and any number of medicaments to other harmless products.

Due-Process Objections

Although it can no longer be maintained that a regulation of interstate commerce is invalid merely because the interstate transportation of harmless products is prohibited, the power to prohibit interstate transportation has never been held to be unlimited. Decisions sustaining prohibitions of the interstate transportation of goods and persons have decided only that the particular legislation involved did not transcend either those limits on the commerce power implicit in the conception of what constitutes regulation or those based on the conception of what constitutes due process of law. Thus, even though it be assumed that a Congressional prohibition of the shipment in interstate commerce of uniodized salt for human consumption as a means for controlling endemic goiter would be within the power of Congress to regulate interstate commerce, such a prohibition would be subject to the requirements of due process of law under the Fifth Amendment. That the validity of Congressional prohibitions of interstate commerce is subject to such requirements has been clearly established by many leading decisions of the Supreme Court of the United States: *Champion v. Ames*, 188 U. S. 321, 23 S. Ct. 321 (1902); *Hoke v.*

U. S., 227 U. S. 308, 33 S. Ct. 281 (1913); *U. S. v. Darby*, 312 U. S. 100, 61 S. Ct. 451 (1941); *Carolene Products Company v. U. S.*, 323 U. S. 18, 65 S. Ct. 1 (1944).

The tests of due process of law are not very definite and the cases in which acts of Congress have been invalidated for violation of the due-process clause of the Fifth Amendment are relatively rare. However, it has been clearly established that the requirement of due process of law imposed on the federal government is the same in principle as the requirement of due process of law imposed upon the states by the Fourteenth Amendment (*Twining v. New Jersey*, 211 U. S. 78, 29 S. Ct. 14 (1908)), and the specific requirements of due process have been set forth in many decisions. Such requirements are clearly specified in *Nebbia v. New York*, CCH TRADE REGULATION REPORTS (Supp. 1932-1937) ¶ 7006, 291 U. S. 502, 54 S. Ct. 505 (1933) at page 525:

> The Fifth Amendment, in the field of federal activity, . . . and the Fourteenth, as respects state action, . . . do not prohibit governmental regulation for the public welfare. They merely condition the exertion of the admitted power, by securing that the end shall be accomplished by means consistent with due process. And the guaranty of due process, as has often been held, demands only that *the law shall not be unreasonable, arbitrary, or capricious, and that the means selected shall have a . . . substantial relation to the object sought to be attained. . . . because the reasonableness of each regulation depends upon the relevant facts.* [Italics supplied.]

Implicit in this definition are three separate requirements: (1) Fundamental rights must not be infringed; (2) the regulation must not be unreasonable, arbitrary or capricious; and (3) the means must have a substantial relation to the end.

In the development of American constitutional law, the Supreme Court has shown no tendency to confine the words in the Fifth and Fourteenth Amendments which define the interests protected. Rather, it has given to terms such as "liberty" and "property" the widest scope. The right to carry on a business free from unnecessary and unjustifiable interference has frequently been identified with the property rights reserved in these amendments (*Truax v. Corrigan*, CCH TRADE REGULATION REPORTS (Supp. Vol. V) ¶ 5601, 257 U. S. 312, 42 S. Ct. 124 (1921)). That the right to carry on the business of producing and selling salt is such a right is indisputable. The extent to which this right may be altered, restricted or destroyed in proper cases is the crux of the problem.

It is apparent at the outset that the mere definition of the specific requirements of due process furnishes no certain standard as to what prohibitions are unreasonable, arbitrary and capricious or as to what means will be regarded as not having a substantial relation to the end sought to be accomplished. "Arbitrary," "unreasonable" and "capricious" find no definitions in written law. Thus, the kinds of exclusions which have been successful, the comparative weight given by the Supreme Court to the rights intended to be advanced by exclusionary legislation and the rights restricted by it, and the relation between articles excluded and the objectives of the particular legislation involved must form a basis for measuring the validity of any legislation excluding uniodized salt from interstate commerce.

The first case sustaining legislation excluding harmless articles from interstate commerce was the so-called Lottery Case, *Champion v. Ames*, cited above. This case upheld a federal statute prohibiting the shipment in interstate commerce of lottery tickets. The objective of the statute was the suppression of gambling involving the use of such tickets. It was apparent that such gambling could and would be suppressed to a considerable extent by the means adopted by Congress. The means selected had a direct and substantial relationship to the objective sought to be attained. Of the rights involved—the right of individuals to engage in the business of producing and selling gambling devices and the right of the federal government to prevent the use of interstate commerce as the agency to promote immorality, dishonesty or the spread of evil—the latter was deemed by the court to justify a substantial restriction of the former.

The Supreme Court also had occasion to consider similar objectives, means of accomplishing such objectives and rights in cases involving Congressional exclusions from interstate commerce of stolen motor vehicles,[23] kidnapped persons,[24] and women for immoral purposes.[25] In each case, the legislation under consideration was designed to suppress some form of criminal activity, the means adopted was the exclusion from interstate commerce of articles obtained by, or persons essential to, such activity, and the right of the federal government to prevent the use of interstate commerce as the agency for criminal activity was deemed by the court to justify an exclusion from interstate commerce. In each situation, the means selected by Con-

[23] *Brooks v. U. S.*, 267 U. S. 432, 45 S. Ct. 345 (1925).

[24] *Gooch v. U. S.*, 297 U. S. 124, 56 S. Ct. 395 (1936).

[25] *Hoke v. U. S.*, cited above.

gress had a direct and substantial relationship to the object sought to be obtained. Additionally, in the cases involving stolen motor vehicles and kidnapped persons, the Court alluded to the fact that Congress can shape its policy so as to help state law enforcement, it having been noted that many states had criminal statutes prohibiting the use or sale in intrastate commerce of stolen motor vehicles and outlawing kidnapping.

A federal statute excluding convict-made goods from interstate commerce was sustained in *Kentucky Whip & Collar v. Illinois Central Railroad Company*, 299 U. S. 334, 57 S. Ct. 277 (1937). The objective of the statute was to prevent the dislocation in pricing of interstate goods. The rationale was that goods produced under standard labor conditions should not be subject to competition from goods produced by convict labor. Again, the relationship between the means adopted and Congressional objectives was substantial.

Cases sustaining legislation excluding harmful, illicit and deceptive products from interstate commerce, although not directly analogous, throw some light on the problem at hand. In *Hipolite Egg Company v. U. S.*, 220 U. S. 45, 31 S. Ct. 364 (1911), the validity of the forerunner of the present Federal Food, Drug, and Cosmetic Act—the Wiley Act of 1906—was sustained. The act was designed to protect the public from adulterated or misbranded products and, in deciding that the exclusion of such products from interstate commerce was a proper exercise of Congress' power to regulate interstate commerce, the Court emphasized the fact that the act dealt with illicit articles—articles debased by adulteration. The federal statute excluding diseased livestock from interstate commerce was sustained for similar reasons in *Reid v. Colorado*, 187 U. S. 137, 23 S. Ct. 92 (1897). In each of these situations, the means selected was the exclusion from interstate commerce of the adulterated, misbranded or offensive article or thing. The existence of a substantial relationship between the objectives of such legislation and the means adopted to accomplish such objectives is obvious.

An exceptionally good case for measuring the validity of proposed federal legislation excluding uniodized salt from interstate commerce is *Carolene Products Company v. U. S.*, cited above, which sustained the validity of the Filled Milk Act of 1923. In the Filled Milk Act of 1923, Congress declared "filled-milk" products to be adulterated

articles of food, injurious to public health, and the sale thereof a fraud on the public. The situation in need of remedy was the upsurge in the sale of filled milk, an *artificial* product. Filled-milk products were made by separating out the butterfat content of whole milk, adding a coconut oil or other substitute in its place and reducing the volume by evaporation.

The possibility and actuality of confusion, deception and substitution were appraised by Congress as follows:

> The compound can be made more cheaply than the regular article. . . . Filled milk is sold under various trade names. . . . The manufacturers cannot sell it as milk, but it is put up in the same size cans as regular condensed milk, and the evidence before the committee shows that it is advertised by the retail dealers as milk and evaporated milk. Storekeepers sell it with the statements that "it takes the place of milk," "just as good as condensed and much cheaper," "nothing better on the market," "takes the place of condensed milk." Instances have been found in which the coconut fat was mixed with milk and sold for cream; the compound has been used for making ice cream . . . . In many cases retailers sell the compound for the same price as the straight evaporated milk, although the price per 1-pound can to them is about 3 cents less. A number of surveys in various parts of the country show that the compound is sold largely in sections inhabited by people unable to read English and sections inhabited by people of limited means, and not sold at all in better residential districts. [H. Rept. 335, 67th Congress, 1st Session, page 2. Cf. also S. Rept. 987, 67th Congress, 4th Session, page 3.]

The danger that the uninformed would confuse filled-milk products with whole-milk products and be deprived of the nutritional elements of whole-milk products was clear and substantial. The existence of such danger was the sole basis upon which the validity of the Filled Milk Act of 1923 was sustained (*Carolene Products Company v. U. S.*, cited above, at page 7 of the opinion).

It should be observed that the basis used to sustain the validity of the Filled Milk Act of 1923 does not exist as a basis for sustaining the validity of federal legislation excluding uniodized salt from interstate commerce. This becomes obvious when the following facts are considered:

(1) Such federal legislation would exclude the *natural product*, uniodized salt, from interstate commerce. The Filled Milk Act of 1923 excludes the *artificial product*, filled milk, from interstate commerce.

(2) No beneficial ingredient is removed during mining or processing of uniodized salt produced for table and kitchen purposes whereas the butterfat content of whole milk, a beneficial and nutritional element, was removed in the manufacture of filled-milk products.

(3) Such federal legislation would require the salt industry to *add* a medicament to a *natural* product. The Filled Milk Act of 1923 prohibited the removal of a natural and beneficial element from a natural product.

(4) Filled-milk products were lower-priced, competitive substitutes for whole-milk products. There is no competition or price differential between uniodized and iodized salt, and iodized salt can never be regarded as being a substitute for uniodized salt.

Although the Supreme Court has many times expressed a reluctance to interfere with legislative conclusions as to the necessity for exclusionary legislation, it has been clearly established that the reasonableness of each prohibition of interstate commerce depends on facts relevant to the situation and that the constitutionality of a statute predicated upon a particular state of facts may be challenged by showing to a court those facts were nonexistent or have ceased to exist (*U. S. v. Carolene Products Company*, 304 U. S. 144, 58 S. Ct. 788 (1937); *Borden's Farm Products Company v. Baldwin*, CCH TRADE REGULATION REPORTS (Supp. 1932-1937) ¶ 7251, 293 U. S. 194, 55 S. Ct. 187 (1934); *Chastleton Corporation v. Sinclair*, 264 U. S. 543, 44 S. Ct. 405 (1923)). It has also been established by many decisions, including those cited above, that a statute would deny due process of law which precluded the proof in judicial proceedings of facts which show, or tend to show, that a statute was unreasonable, arbitrary and capricious and that the means selected had no substantial relationship to the end sought to be obtained.

It is evident from the above cases that the Supreme Court of the United States has not followed the extreme doctrine of judicial abnegation found in *Powell v. Pennsylvania*, 127 U. S. 678, 8 S. Ct. 992 (1888), a case sustaining a conviction for the sale of oleomargarine contrary to the provisions of a criminal statute. In that case, the Court said that conducting investigations of fact entering into questions of public policy is not part of the Court's function. The adoption of the doctrine that facts upon which constitutionality depends will, and should be, determined by the Supreme Court is not of recent occurrence. As early as 1926, in *Weaver v. Palmer Brothers Company*, 270 U. S. 402, 46 S. Ct. 320 (1925), the Supreme Court refused to follow the extreme doctrine of *Powell v. Pennsylvania*. The *Weaver* case involved a Pennsylvania statute, which on the ostensible ground

of protection to health, forbade the use of shoddy in the manufacture of bedding. Contrary to its avowal in the oleomargarine case, the Court did investigate the facts and found that "there was no evidence that any sickness or disease was ever caused by the use of shoddy" and, in any event, "all danger . . . may be eliminated by sterilization."

Since it is largely a question of fact as to whether a certain activity prohibited by law is in truth detrimental to the public health or morals, it goes without saying that all relevant facts should be determined and available for presentation to the Supreme Court in any case contesting the constitutionality of compulsory-iodization legislation. Federal legislation excluding from interstate commerce all uniodized salt produced and sold for table and kitchen purposes, if similar to the Bolton bill proposed in 1947, would have as its objective the elimination and control of endemic goiter in the United States. Thus, the facts which should be relevant in any judicial determination of the constitutionality of such legislation are easily determinable.

Basically, facts as to the following would be relevant: (1) the nature and extent of the endemic-goiter problem in the United States today, (2) the cause or causes of endemic goiter, if known, (3) the extent to which uniodized salt, the product to be excluded from interstate commerce, causes endemic goiter, (4) the extent to which endemic goiter has been and can be eliminated and controlled by means other than the one ultimately selected by Congress, (5) the extent of the market for uniodized salt in the United States, (6) the nature and extent of the burden upon producers of salt attendant on compliance with such legislation and (7) the extent to which endemic goiter can be eliminated and controlled by exclusion of uniodized salt from interstate commerce, including facts as to the number and production of salt producers not subject to such legislation located in any endemic-goiter area.

Many of the above facts have been set forth under "Regulatory Objections," above. There remains, however, the question of the weight and importance which would be given to such facts by the Supreme Court in reaching an ultimate decision as to the constitutionality of a federal statute excluding uniodized salt from interstate commerce. From an analysis of the cases sustaining federal statutes excluding articles and persons from interstate commerce, it is apparent that considerable weight is given to facts establishing that a particular

evil does exist, the extensiveness of the evil, and the existence of a substantial relationship between such evil and the means selected for its elimination.

In the lottery-ticket, motor-vehicle, kidnapping and white-slave-traffic cases, the evils involved were extensive and criminal in nature. The exclusion of the articles or persons essential to the perpetration and perpetuation of such evils—the means selected for their elimination—had a direct and substantial relationship to the objective of Congress. Additionally, when the respective interests involved are considered—the right to engage in a form of criminal activity and the right of the federal government to protect health and morals—the constitutionality of the prohibitions involved becomes obvious. The evils involved in the adulteration, misbranding, diseased-livestock, and harmful and deceptive product cases also were extensive, although not criminal in nature according to fundamental concepts. Nevertheless, in each situation, the means selected to eliminate the evil involved had a direct and substantial relationship to the objective sought to be attained.

The picture thus set forth gives the proper perspective for considering facts regarding endemic goiter. That endemic goiter was a health problem in four "goiter belt" counties in the State of Michigan; in Cleveland and Akron, Ohio; and in Huntington and Charleston, West Virginia, during the period from 1900 to 1936 seems clear from surveys made by the medical profession. The incidence of endemic goiters in some of these areas was as high as 38.6 per cent. The current incidence of endemic goiter in any of the above areas is not known. However, available facts as to the incidence of endemic goiter in the four "goiter belt" counties in the State of Michigan suggest that endemic goiter no longer exists as the health problem it was prior to 1936. Surveys have established that while the incidence of endemic goiter in the four "goiter belt" counties in Michigan was 38.6 per cent in 1924, it was only 1.4 per cent in 1951. Additionally, the percentage of goiter surgery in nine large hospitals in the State of Michigan was less than 1 per cent in 1951.

Evidence is lacking that endemic goiter exists throughout the United States as a health problem in need of remedy, so additional perspective must be sought by considering hypothetical situations, the objective being to determine on what basis extensiveness would be measured and how extensive an endemic-goiter evil would have to be

to warrant the exclusion from interstate commerce of uniodized salt. The extensiveness of any endemic-goiter evil that may exist undoubtedly can be measured in several ways. It can be measured by using the national incidence—the percentage obtained by dividing the number of persons in the United States having endemic goiter by its population. It can also be measured by using information covering the number and extent of the areas in which persons having endemic goiter are found, and the incidence of endemic goiter in each such area.

If the so-called "goiter belts" are common to all 48 states or if endemic goiter is found to exist throughout the United States, extensiveness probably would and should be measured by the national incidence. However, if persons having endemic goiter are found only in the "goiter belts" and if such belts are found only in a limited number of states, extensiveness probably would not and should not be measured by the national incidence. To the extent that endemic goiter is a problem in a limited number of areas or states, it becomes a local, rather than a national, problem. In considering the nature and scope of an alleged endemic-goiter evil, the Supreme Court undoubtedly would consider the extent to which endemic goiter is a local problem, along with facts as to its incidence in any areas where it was found to exist.

For example, assume that endemic goiter exists throughout the United States and that the number of persons having endemic goiter and its national incidence are as follows:

Persons Having Endemic Goiter	*National Incidence*
5 persons out of each 1,000	½%
10 persons out of each 1,000	1%
20 persons out of each 1,000	2%
30 persons out of each 1,000	3%
40 persons out of each 1,000	4%
50 persons out of each 1,000	5%
60 persons out of each 1,000	6%
70 persons out of each 1,000	7%
80 persons out of each 1,000	8%
90 persons out of each 1,000	9%
100 persons out of each 1,000	10%
150 persons out of each 1,000	15%
200 persons out of each 1,000	20%

If the national incidence of endemic goiter were 20 per cent, 15 per cent, or possibly even 10 per cent, the health problem resulting from endemic goiter would undoubtedly be extensive and be so

regarded by the Supreme Court. On the other hand, a national incidence of one half of 1 per cent undoubtedly would not and should not be regarded as constituting an extensive evil. Thus, the dividing line probably exists somewhere between ½ per cent and 10 per cent.

However, what if the incidence of endemic goiter were 80 per cent in Michigan, Ohio, West Virginia, Wisconsin, Indiana and Illinois? The national incidence would be over 16 per cent, but the resulting health problem would be confined to six states. What if the incidence of endemic goiter were 5 per cent or 30 per cent in various combinations of states? The following schedules present a few of the many situations that might possibly exist:

5 Per cent

If Incidence of Endemic Goiter Were 5% in Each of the Following:	*Number of Persons Who Would Have Endemic Goiter Would Be:*	*Incidence of Endemic Goiter in United States Would Be:*
(1) Michigan	320,000	.002
(2) Michigan	320,000	
Ohio	395,000	
	615,000	.004
(3) Michigan	320,000	
Ohio	395,000	
West Virginia	100,000	
	815,000	.005
(4) Michigan	320,000	
Ohio	395,000	
West Virginia	100,000	
Wisconsin	175,000	
	990,000	.0066
(5) Michigan	320,000	
Ohio	395,000	
West Virginia	100,000	
Wisconsin	175,000	
Indiana	200,000	
	1,190,000	.0079

(Table continued on following page)

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5 Per cent

If Incidence of Endemic Goiter Were 5% in Each of the Following:	*Number of Persons Who Would Have Endemic Goiter Would Be:*	*Incidence of Endemic Goiter in United States Would Be:*
(6) Michigan	320,000	
Ohio	395,000	
West Virginia	100,000	
Wisconsin	175,000	
Indiana	200,000	
Illinois	435,000	
	1,625,000	.01
(7) Michigan	320,000	
Ohio	395,000	
West Virginia	100,000	
Wisconsin	175,000	
Indiana	200,000	
Illinois	435,000	
Minnesota	150,000	
Kansas	100,000	
Colorado	65,000	
Utah	35,000	
Nevada	8,000	
Missouri	200,000	
	2,183,000	.014

30 Per cent

If Incidence of Endemic Goiter Were 30% in Each of the Following:	*Number of Persons Who Would Have Endemic Goiter Would Be:*	*Incidence of Endemic Goiter in United States Would Be:*
(1) Michigan	1,920,000	1.3%
(2) Michigan	1,920,000	
Ohio	2,400,000	
	4,340,000	2.9%
(3) Michigan	1,920,000	
Ohio	2,400,000	
West Virginia	600,000	
	4,200,000	3.2%

		30 Per cent Goiter Were 30% in Each If Incidence of Endemic of the Following:	*Would Have Endemic Number of Persons Who Goiter Would Be:*	*Goiter in United Incidence of Endemic States Would Be:*
(4)	Michigan		1,920,000	
	Ohio		2,400,000	
	West Virginia		600,000	
	Wisconsin		1,050,000	
	Illinois		2,610,000	
	Indiana		1,200,000	
			9,780,000	6.5%

If a national incidence of about 5 per cent is assumed to be extensive, would the Supreme Court regard a national incidence of 6.5 per cent, resulting from a 30 per cent incidence in six states, as being extensive? To the extent that endemic goiter is not widespread throughout the United States, it would appear that a substantially higher national incidence should be and would be required by the Supreme Court to satisfy the extensiveness requirement implicit in and obviously met in all prohibitions cases to date.

For purposes of the foregoing discussion, it has been assumed that a substantial relationship existed between the means selected and the end sought to be attained. To the extent that such relationship does not exist, the Supreme Court undoutbedly would and should require a more extensive evil, a substantially higher incidence of endemic goiter whether endemic goiter is widespread throughout the United States or is confined to a limited number of states.

The relationship between exclusion of uniodized salt from interstate commerce and elimination of endemic goiter is at best a negative one. Uniodized salt does not cause endemic goiter and uniodized salt is not useful as a remedy for curing endemic goiter. Actually, there is no relationship whatsoever between uniodized salt and endemic goiter. Moreover, endemic goiter cannot be cured by the use of iodized salt. The most that can be established is that iodized salt is a beneficial and useful product for carrying iodine to man and for use in connection with the preventive treatment of endemic goiter. Additionally, when the fact that the causes of endemic goiter are not known is considered, it becomes even more apparent that the relationship between compulsory iodization and the elimination of goiter is remote.

Moreover, in considering whether or not there is the requisite substantial relationship, the Supreme Court undoubtedly would and should consider the fact that endemic goiter has been, and can be, eliminated by voluntary programs as well as the fact that iodized salt has been, and presumably will continue to be, universally available throughout the United States for use individually or in connection with such programs.

In applying the due-process clause, the Supreme Court engages in a task radically different from that engaged in in other fields of law. The task involves a balancing of the interests and dangers involved. It undoubtedly considers the degree of the danger, the economic and social demands fulfilled by the prohibited article, the amount of capital invested in the industries affected and, last, the possibility of accomplishing the objective by less drastic measures. On the basis of known facts, it is believed that compulsory iodization legislation would be held an unconstitutional denial of due process of law under the Fifth Amendment. **[The End]**

• FDA ALTERS RECORD-KEEPING REGULATIONS •

The Food and Drug Administration on February 27 called attention to changes in record-keeping regulations under the Federal Food, Drug, and Cosmetic Act and the Import Milk Act. Following is a summary of records now required to be held by food, drug, device and cosmetic manufacturers:

(1) *Agreements Under the Regulations Exempting Interplant Shipments of Foods, Drugs, Devices or Cosmetics from Certain Labeling Requirements.*—Each party to such an agreement is required to keep a copy until two years after final shipment or delivery of products covered.

(2) *Coal-Tar Colors.*—This provision is now uniform with the other record-keeping regulations. Certificate holders are required to retain their records relating to each batch or lot until two years after the last of the batch is shipped.

(3) *Sea Foods.*—Records on each lot shipped from an inspected plant are required to be kept for two years.

(4) *New Drugs for Investigational Use.*—Records pertaining to such drugs are required to be kept until two years after a new-drug application is made effective or until two years after shipments for investigational use are discontinued.

(5) *Antibiotics.*—There is no change except that after the first two years of the holding period, permanent reproduction—such as microfilm—may be substituted for the original records.

(6) *Insulin.*—Records are required to be kept for two years after disposal of the last of a certified batch.

(7) *Import Milk Records.*—Records formerly kept for one year are now required to be kept for two years.

The Civil-Defense Training Program of the Food and Drug Administration

By L. M. BEACHAM

Mr. Beacham Outlines FDA Preparations for the Possibility of "Extraordinary Needs for Food and Drug Inspection and Control in Attacked Areas"

ON JULY 14, 1954, the President approved Delegation of Authority No. 1 (19 *Federal Register* 4546), by which the Federal Civil Defense Administrator delegated, under the provisions of Public Law 920, responsibility to the Department of Health, Education, and Welfare for planning and promoting civil-defense activities in certain fields where the Department has primary peacetime responsibility. For that fiscal year, and subsequently, the Congress has appropriated funds to carry out the delegation.

The delegated responsibility of greatest interest to the Food and Drug Administration called upon the Department to:

> . . . plan a national program, conduct research, develop technical guidance for States, and direct Federal activities designed to meet the extraordinary needs for food and drug inspection and control in attacked areas.

Naturally, this responsibility was assigned by the Department to the Food and Drug Administration, which promptly developed several programs to meet the obligations. One of the most important—the subject of this discussion—was the training program designed to give fundamental basic training on the nature of special chemical, biological or radiological weapons that might be used to attack us, and the special problems that they would engender for those engaged in preserving, protecting and restoring our food and drug supply during emergency. We made immediate plans to present this basic information to state and local food and drug officials throughout the Nation.

However, before we could carry out such a program it was necessary to acquire the pertinent information; train instructors; and

The Author Is the Assistant Chief, Division of Food, Bureau of Biological and Physical Sciences, FDA

plan a curriculum, obtain suitable films, slides, and other graphic and visual aids to augment the lecture material, and radiological detection and measuring instruments for demonstration and training purposes. During the fall of 1954, four instructors were appointed who had had active food and drug experience. Two came from our field inspection force—skilled and experienced inspectors; a bacteriologist was transferred from our Division of Microbiology; the fourth was a former Food and Drug Administration chemist who came back with us by reinstatement. None of these had had more than casual experience in civil-defense work. They were therefore given intensive training in nuclear physics, radiological health problems, the fundamentals of chemical and biological warfare, and current civil-defense practice.

Planning of Training Course

With the knowledge thus acquired, a five-day training course was planned in which the fundamentals of these subjects, necessary for understanding the problems that might confront a food and drug official after an attack, would be given. It was essential that the instruction be in simple, down-to-earth language, as free as possible from technical terminology, with mathematical formulas kept to the barest minimum, and that it be pertinent to the operations and needs of those taking the course. The task of preparing the necessary lectures, and illustrating them with slides, graphs, charts, pictures and demonstrations, was apportioned among the four instructors. From the film libraries of the Armed Services, the Atomic Energy Commission, the Civil Defense Administration, and other sources, we were able to select more than a dozen very excellent training films to be incorporated in our five-day course.

Fortunately, in the late spring of 1955, Operation Cue was held in connection with the weapons-testing program at the Nevada Proving Ground. In this operation, the Federal Civil Defense Administration exposed houses, industrial structures and mechanical installations of various kinds to the heat, blast and radiation effects of an atomic explosion. We arranged to have one of our instructors present at the test site, and he took some very impressive pictures of the buildings and their contents before and after the blast. These made a very valuable addition to our visual-aid material. His firsthand account of how he was knocked off his feet while viewing the explosion from a distance of five miles was also calculated to capture the attention of his audience.

We felt it was necessary to have a textbook or manual to assist those attending our classes and to serve them as a reference book and aid to memory later. Our aim was to prepare a publication that would give men who had neither the time nor the desire to delve deeply into the mathematical and theoretical intricacies of nuclear physics and other specialized sciences sufficient information about nuclear, radiological, chemical and biological warfare agents to enable them to meet problems that they might face after an attack. Since the lectures in the classroom were to be kept as free as possible of mathematical calculations and formulas, more were given in the handbook—but every effort was made to include only those that would contribute directly to a better understanding of the broad principles involved and to their practical application. The objective of the training course was to bring out in the lectures, and to record in the manual, information that, first, would enable a food and drug official, confronted with the aftermath of an attack, to decide what must be done and how it could be accomplished with the least effort and least danger to his personnel; that, next, would give enough of the theoretical background to help him understand the reasons for the things he should or should not do; and, finally, that would refresh his memory on certain portions of the basic sciences that he would find useful in performing and understanding his civil-defense responsibilities.

With this in mind, we arranged the material in the manual in a somewhat unorthodox fashion. Part I comprised material describing and explaining some of the problems that attack might bring, giving directions for salvaging, reconditioning, and maintaining proper sanitary conditions and for measuring and evaluating radioactive contami-

nation. Under the subject of "salvage," we included chapters on decontamination after chemical or biological attack. The second part dealt with the nature of possible chemical and biological warfare agents; with the situations where they might be used; with nuclear explosions and fission products; and with radioactivity. Part III contained a brief review of certain useful principles of mathematics, physics and chemistry; a limited number of charts; tables; a glossary; a bibliography; and other data that we felt had a place in such a manual. The finished publication ran to 188 pages and, with a genuine apprehension that we might be misspending our funds by buying too many, we ordered 5,000 printed.

Extensive Requests for *Manual*

To our surprise, the manual acquired an unexpected popularity. Since it was entitled *Civil Defense Information for Food and Drug Officials*, we had anticipated that it would be desired only by those who attended our training course. However, when the courses got under way, we soon began to receive requests for it from food and drug officials who had not been able to attend the classes and then from others who were not food and drug officials at all but who had responsibilities and an interest in civil defense. We soon saw that we had not had printed enough of the manuals to take care of this demand, and so arranged for a reprinting. This, too, has been exhausted—making a total of 7,900 copies that have been distributed, largely on request, throughout our country and many foreign countries. At the present time, a revised and expanded edition is being prepared, for which we already have numerous requests.

Returning to the development of the training course itself: By the first of June, 1955, we had everything ready to begin. Feeling that we should make a test run on some of our own people, we assembled a volunteer class of about 20 from the personnel of our Washington offices and laboratories, and presented the material to them, following the exact schedule we had planned. Aided by the experience gained in actually delivering the lectures and putting on demonstrations, and with the assistance of the suggestions and evaluations freely given by those who had sat and listened, we were able to make numerous improvements before we actually "put the show on the road." The four instructors then were divided up into two two-man teams, to give the training course independently and concurrently in different places. Our initial efforts were made, during the last week in June,

before classes in Richmond and Baltimore. We were truly gratified by the interest and the enthusiasm shown by those attending the classes. From their reactions, and with their suggestions, we were able once more to make changes in our teaching material designed to improve and make it more effective. This consisted largely in rearrangements in the order of presentation and in shifts of emphasis on certain parts of the subject matter, giving more time and attention to some parts of it and treating other parts in less detail. For example, we found our students were eager to spend more time actually using Geiger counters in locating and measuring "hot" sources than we had originally allowed.

With the beginning of fiscal year 1956, we felt that we were at last ready to embark upon the main part of our program and we accordingly set about carrying out a schedule that called for presentation of the training courses in approximately 50 cities, located in 46 states, during the ensuing year. This required each team to be in travel status more than half the time. This schedule was adhered to with practically no changes except a few shifts in dates where it was found that the dates originally selected were not convenient for those who wished to attend. Realizing that the best instruction could be given before small, informal groups, where there would be the opportunity for questions and discussions, and an atmosphere that would encourage them, we had at first planned on an average class size of perhaps 16, with a maximum of 20. We soon found that we could not keep the classes down to this size. Our average class attendance was more nearly 30, and often higher. At Albuquerque, New Mexico, we had our largest class, with 70 attending. All in all, during the first year of the training program for state and local food and drug officials, more than 2,000 attended the basic five-day course and many of them later attended a three-day refresher course that we subsequently developed and gave to state and local officials in several cities, in response to their requests.

The training courses for state and local officials continue at present on a "by special request" basis, and more than 65 of the five-day basic, or three-day refresher, courses have now been given. Those who attend and complete either course are given individual certificates attesting to that fact.

Meanwhile, at the request of the Food and Drug Administration, the National Academy of Sciences-National Research Council ap-

pointed a civil defense-foods advisory committee composed of eminent men in the field of food processing and research. The function of this committee was to study the vulnerability of the food industries of America to surreptitious attack by an enemy using chemical, biological and radiological warfare agents. The committee made an intensive study lasting several months and, in November, 1955, it rendered a report to the Food and Drug Administration in which it took each important segment of the food-processing industry separately and showed the points where, in the course of normal processing, the product was open to attack by saboteurs using one or more covert warfare agents. The committee's findings were disquieting. One of its conclusions was that:

. . . certain segments of the food industry are extremely vulnerable to covert activity with Biological or Chemical Warfare agents, or both, and possibly to Radiological Warfare agents, because of the characteristics of manufacturing processes, the nature of certain foods and their ingredients, and the general unawareness of management, technical staff, and labor concerning the potential problem . . . .

It also concluded that:

. . . under present conditions of food manufacture, packing, and distribution, it would be possible to contaminate sufficient food with biological or chemical agents or possible radiological warfare agents to impair the health or endanger the lives of large numbers of people scattered over wide areas in the U. S. A.

The committee concluded further that:

. . . the fact that the food industries are unaware of the hazard of covert use of chemical, biological, and/or radiological warfare and that the Federal Civil Defense Administration and other agencies are unfamiliar with the complexities of food processing, makes the problem of the covert use of [these] warfare agents acute and serious.

Advisory Committee's Recommendations

To remedy this potentially dangerous situation, the committee made certain specific recommendations, among them being that:

. . . the FDA apprise the food management and technical personnel of the processing, transportation, and warehousing industries of their vulnerability to the effects of overt and covert special weapons attack. Two means of accomplishing this may be by direct contact with a few members of the industry who, in turn, would contact others, and through trade associations, scientific societies, etc.

Another recommendation was that:

. . . the FDA provide special trained personnel to work with and encourage food trade associations and pertinent scientific societies to establish local committees in metropolitan areas to study local and particular industry needs and to assist in laying plans for, and training management and technologists in, steps to be taken in an emergency.

As we neared the completion of our initial program of training state and local food and drug officials, we began to make plans to use our training resources to carry out the recommendations above. With this in mind, we began by approaching the trade organizations of the canning industry and of the frozen-food industry. We found these organizations quite willing to cooperate with us in developing programs by which the members of their industry and, particularly, those having technological responsibilities could be informed of the potential hazards under which they operate and of the steps that might be taken to reduce—if not to remove—such hazards. While arrangements were being made to make the program known to those interested and to schedule training schools in those areas of the country where canning and freezing operations are most extensive, our instructors reorganized and reorientated their training material to adapt it to technically trained industry personnel, to make it specifically applicable to the particular processes employed and to shift some of the emphasis on the problems that might result from open attack to those created by the cunning manipulations of a trained and skillful enemy saboteur. At the present time, one such training school has already been completed and others are scheduled in the near future for the East, the Midwest and the Pacific Coast areas. Our current plans are to extend this program to other parts of the food processing and distributing industries, such as the baking industry, the dairy industry, the bottlers of soft drinks and the operators of cold-storage warehouses.

While we were making the above plans and carrying some of them to fruition, we were also able to add substantially to our stocks of physical equipment that would be useful for training and indispensable in case of actual emergency. Notable among these were a mobile laboratory and a tractor to haul it. This laboratory we obtained from the pool of surplus defense material, and we had it overhauled and equipped for use in detecting and measuring fall-out or other sources of radioactivity in or on food. We hope to use it at the next series of tests at Nevada Proving Ground to give our instructors practical experience in measuring and removing fall-out from foods and other materials. This experience, and the resulting increase in our knowledge, will better enable us to discharge the continuing responsibility that was delegated to us to:

. . . plan a national program, conduct research, develop technical guidance for States, and direct Federal activities designed to meet the extraordinary needs for food and drug inspection and control in attacked areas.

[The End]

By EUGENE H. HOLEMAN

GUARDING THE GULLET IN TEN
TO DROWN THE OPERATOR TO PREVENT FOO

THE PEAKS AND VALLEYS of food and drug law enforcement in the State of Tennessee do not follow—even under a uniform-type food, drug and cosmetic act—the pattern found in the enforcement of the Federal Food, Drug, and Cosmetic Act. As would be expected, with closer contact with the persons coming under regulatory control, personalities often color and influence the application of the laws and regulations, and, of course, the lower courts, general sessions courts and even grand juries and circuit courts take on a more personal air. This is a good condition in the great majority of the cases involved; in a few, it results in unexplainable reverses.

It must be recognized also that these close contacts between the regulated food and drug industries, the legal profession and courts, and the control officials result in many instances of compliance with the act with the least amount of disturbance to the industry and the maximum in consumer protection. For example, in Tennessee during the year 1956, 226,561 pounds of food were removed from edible channels by voluntary destruction or diversion to animal-food channels.

There is also a general willingness to take measures to remove cause for bacterial contamination and to upgrade the sanitary conditions in plants when the inspectors explain the need for them. Informal hearings, with a district attorney general or assisant state's attorney general as legal advisor, have resulted in increased respect for the food and drug act and a better understanding of the legal aspects of routine inspection, analysis, and plant and product examination.

Even an informal hearing can, on occasion, take an extralegal turn. After failing through the regular inspection and notice methods to get an owner of a small combination chicken-slaughtering and cream-buying establishment to separate and clean up his business, I

IN TENNESSEE: IS IT NECESSARY TO HAVE FOOD ADULTERATION?

The Author, Superintendent and State Chemist, Division of Food and Drugs, Tennessee Department of Agriculture, Presents Sidelights on Food and Drug Control in His State—"Some Difficulties and Interesting Situations"—and Makes Recommendations for Effective Enforcement

cited him in for a hearing. He readily admitted to the existence of the conditions found. Therefore, before our assistant attorney general could say anything, I said: "You are fined $50 for offering adulterated food for sale." When the offender rose and offered to pay his fine, I had to say: "Your fine is suspended pending reinspection." I neglected to tell him that I didn't have authority to impose a fine. He didn't clean up, so we broke even on that round.

Definitions of "Misbranding" and "Adulteration"

Both the federal act and the state acts, I believe, should be broad in their definitions of "misbranding" and "adulteration." There are just too many applications of these sections to specify each type of violation. The general nature of the laws, however, makes it difficult to secure convictions, in many instances. Although the Tennessee act has not yet been amended in this respect, several other states have had to change theirs. This weakness has shown up particularly in cases involving the adulteration of meat with sulfites and benzoates.

Here is an example of an interesting case we lost, involving the treatment of ground meat with sulfite: Ten samples were taken by an inspector from five different markets. All markets are owned by one company. Seven samples were loaded. The case was prepared by the district attorney general with the utmost care. In the meantime, the defendant was running daily newspaper ads to denounce the state

officials. At the trial we presented several qualified chemists and technical people to trace the presence of the preservative in the food product, and the harmful effect of its use. Samples were exhibited showing the results secured from sulfite treatment. The many witnesses presented by the defendant denied any knowledge of the use of a preservative, even though one of the official inspectors had chased after a butcher running from a store with a five-pound can of "Preservaline" under his arm.

One of the most interesting parts of the scene was the presence of 25 or 30 hillbilly entertainers to cheer the defense witnesses on. The high point was reached, however, when the defendant said:

> Before this trouble came up, I wanted to give the Commissioner a pony. He refused to take just an ordinary pony and asked for a mare pony. This I refused, because he would start raising more ponies with this mare pony and put me out of the pony business.

Well, there you are. The judge dismissed the case and the pony story made the headlines. The judge said that we won the case, but didn't give the defendant sufficient notice.

Regulations defining such type of adulteration do not help much. We have one, and used it in the case above. The defense attorney said: "That's just another lawyer's opinion in Nashville."

State on Trial?

In cases of this type and others, the state finds itself on the defense more than the defendant—proving sampling, delivering and testing methods. I have no objection to furnishing such proof. However, some of the state acts give some help to the food and drug officials by stating in part: "Certified copies of inspection and analysis reports are *prima facie* evidence of the facts contained therein." Several also name the specific preservatives prohibited. The states must have need of these sections.

With these kinds of difficulties showing up, under the uniform-type food and drug law, on the addition of chemicals which have been prohibited for years, it is anticipated that a great deal of fun will be had with a "chemical additive" section of a general nature.

Judge Henry Todd, of the Davidson County General Sessions Court, made me feel mighty low when he threw out a case I brought before him on the substitution in frozen deserts of butterfat with beef and vegetable fats. He ruled that, in drawing up the warrant, I had

neglected to prefix the code section with the word "Tennessee." Since I had written "Code Section 52-103 a," no one knew whether I was prosecuting for a violation of Tennessee's code or the codes of Arkansas or Mississippi or the State of Maine. I felt better, however, when he publicly proclaimed me the "guardian of the gullet" in Tennessee.

Interesting Regulatory Problem

Two years ago, a regulatory problem came up on the inspection of an egg-breaking plant. Conditions became so bad in the plant that two inspectors were assigned to the operation—one in the processing area and one at the receiving platform. We wanted the plant to stay open to take up surplus eggs in the area and to provide limited employment for the community. Relations between the operator and the inspectors went from bad to worse, so I informed the company that we could not furnish continuous inspection, that the inspectors would be removed and that seizures and injunctive and other court action would be taken on the basis of spot inspections.

The company appeared to agree to this procedure. However, when a spot inspection was made a few days after the inspectors were taken out, it was found that the company had closed down.

I thought this ended the problem. A month later, however, the commissioner called me to his office. He had a file, at least 18 inches thick, containing affidavits, letters, profit-and-loss statements, and various and sundry receipts for egg purchases, labels, payroll records, and so on. The owner had been in to see the governor and had left the file with him. The governor was told that we (1) interfered with interstate commerce; (2) hindered his operation so much that it was impossible to operate at a profit, so he was forced to close; (3) caused his personnel to quit; and (4) tried to enforce wage-and-hour regulations; and, finally, that the two inspectors had tried to drown the plant operator. Nothing was mentioned about the quality of the food being handled except that I didn't know "an egg from a potato." I called in the two inspectors and we wrote a brief summary of the experience for the commissioner to transmit to the governor.

Possible Explanation of "Drowning" Charge

The drowning charge must have originated from the fact than an inspector had invited the plant operator to go fishing with him one day. (A directive was then sent to all inspectors not to invite food and drug people to go fishing or hunting with them.)

The conclusion of the above episode was the sending in of another operator to manage the plant the next year. Pleasant relations have been the rule since.

This paper is not a review of the many phases of food and drug control in Tennessee. The Food and Drug Division of the Tennessee Department of Agriculture enforces the food, drug and cosmetic act; sanitary food-handling law; egg law; oleomargarine law; meat-inspection law; pesticide law; labeling laws; kosher food laws; and horsemeat and locker-plant laws. Chemical work is done for the dairy division and the feed and fertilizer division and some toxicological work is done for law-enforcement agencies. It would, therefore, take some time and space to go into the entire regulatory program. I have attempted to mention some difficulties and interesting situations met with in the enforcement of a uniform-type food and drug act.

Enforcement Suggestions

My recommendations are:

(1) Work closely with other health and regulatory agencies in order to prevent overlapping of work, to prevent irritating and expensive changes in the food and drug plant because of different interpretations of regulations, and to secure the maximum in consumer protection. During the past several weeks, officials of the Tennessee Department of Agriculture have been meeting with the Tennessee Department of Public Health and representatives of milk producers and milk processors. Out of these meetings will come concrete recommendations to the Tennessee Legislature (now in session) to amend our present laws and establishment of a cooperative basis for future work in dairy-products control. Bread and bakery-products labeling and advertising and the standards for bread need study for possible changes in the present standards or prosecution for violation of present standards and false advertising. We are working closely with the federal Food and Drug Administration, the Food Protection Committee of the Nutrition Council and with other states on these major problems.

(2) Enact in each state a uniform-type food, drug and cosmetic act with specific sections added to correct troublesome practices in the state or areas involved.

(3) Work closely with the state and district attorneys general.

(4) Strive to improve the equipment of state and municipal laboratories and to increase the pay scale of state and municipal personnel.

(5) Take your work seriously, but not yourself.

Developments and Complications

Food, drug, cosmetic and chemical control, in the light of present-day developments from research and production methods, is more complex and more difficult. It must be flexible enough and prepared by experience and training to meet present-day nutrition knowledge and labeling and advertising claims. Areas of adulteration or misbranding are possible today which were never considered five, ten or 15 years ago. It is a big job, yet encouraging prospects for adequate consumer protection are evident from many sources. **[The End]**

CALIFORNIA LEGISLATURE PAYS TRIBUTE TO MILTON P. DUFFY

On January 25, both houses of the California Legislature adopted Senate Concurrent Resolution No. 53, congratulating and commending Milton P. Duffy, chief of California's bureau of food and drug inspections, on his receipt of the Harvey W. Wiley Award for outstanding administration of the food and drug laws. The resolution read, in part, as follows:

"WHEREAS, Milton P. Duffy has rendered outstanding service and displayed an unparalleled devotion to duty as Chief of the Bureau of Food and Drug Inspections, State Department of Public Health, since the establishment of that agency in 1921; and . . .

"WHEREAS, the Association of Food and Drug Officials of the United States duly considered all persons most worthy of receiving an award made on the occasion of the fiftieth anniversary of the enactment of the first federal food and drug law and the sixtieth anniversary of the founding of that association; and

"WHEREAS, The Association bestowed the award, which is named in honor of the author of the Nation's first pure food and drug law, upon Milton P. Duffy 'In recognition of outstanding service and devotion to duty in administering the food and drug laws of his state—and the leadership and guidance he has provided to his fellow workers throughout the Nation'; and . . .

"WHEREAS, It is fitting and proper that the Legislature and the people of the State express their appreciation to him for his long career devoted to their interests, and join the Association of Food and Drug Officials in honoring him; now, therefore, be it

"Resolved by the Senate of the State of California, the Assembly thereof concurring, That the Legislature congratulates Milton P. Duffy on his receipt of the Harvey W. Wiley Award, commends him for the able administration and leadership which won that award, and expresses to him sincerest appreciation for four decades of devoted service to the people and State of California . . . ."

By LEONARD J. ROBBINS

THE AMERICAN PHARMACEUTICA[L] PRESENT PROBLEM[S]

UP TO THE MIDDLE THIRTIES, pharmaceutical patents were fairly rare animals. Although the chemical industry as a whole was then certainly flexing its muscles, few would have predicted that within 20 years pharmaceuticals would be manufactured and distributed on a world-wide scale and on a highly competitive basis; that their names would no longer be the esoteric language of doctors but would be household words; and that patent protection would have become a major objective of research and also a major problem of research policy.

The changing environment or climate of research in this new era of economic expansion, and the growing realization of the interdependence of research and patents, is well illustrated by the early histories of penicillin, on the one hand, and the sulfa drugs, on the other. Penicillin crept onto the scene more or less unheralded, and essential disclosures were made in technical papers without any thought of patent protection. With the sulfa drugs, on the contrary, the research here and in Europe just before the war was covered by patents in a large number of countries; this was one of the first instances of the recognition from the outset of the importance of a new pharmaceutical product on an international scale. How large is the interest of the pharmaceutical industry here in foreign patents? As far as I am aware, no numerical survey has been made. The figure of interest is the number of patent applications filed abroad each year. They represent the direct fruits of research, and they also represent hope. Some fall by the wayside for various reasons before becoming issued patents. There are well over 100 countries throughout the world which have patent laws. Only the major countries publish detailed statistics. However, an analysis of these statistics plus some

MANUFACTURER AND FOREIGN PATENTS—AND FUTURE TRENDS

The Writer—Attorney, New York City—Notes That in the International Field This Industry Has More Potential Foreign Sources of Competitive Infringement Than Any Other. He Addressed the American Pharmaceutical Manufacturers' Association on December 10, 1956, in New York City

guesswork and extrapolation leads to the conclusion that the United States pharmaceutical industry at the present time is filing several thousand foreign patent applications a year. This means that the industry is probably now filing about as many—or almost as many—foreign applications as domestic applications.

This ratio is considerably greater than for the chemical field in general and certainly much greater than in other fields. What is the reason? It is clearly due to the nature of the pharmaceutical industry itself, which can operate in small units based on skills rather than large capital investments. Therefore, even the smaller countries can be competitors. Consequently, an important new United States invention must be filed in a large number of foreign countries if adequate protection is to be obtained. To put it another way: In the international field, the United States pharmaceutical industry has the inherent occupational misfortune of being faced with many more potential foreign sources of competitive infringement than any other industry. Anything of value that is left unprotected is likely to be appropriated.

I will touch briefly on a situation which dramatically illustrates the disruptive effect of lack of patent protection. The Italian patent office has refused to grant patents for pharmaceuticals for many years. This is a complex situation involving much politics and litigation.

However, the net result is that in the absence of patents the Italian industry has been able to appropriate and copy many important United States pharmaceutical products and those of other foreign countries. Furthermore, such products have been exported from Italy to numerous other countries where patents do exist. Since infringement cannot be stamped out at its source in Italy, such export can only be stopped piecemeal by the laborious and expensive process of bringing individual infringement suits in each country. Few are willing to engage in such a battle unless a major commercial situation is involved. By analogy, if an important invention is not protected in any of the principal producing countries, they can become similar sore spots. In view of the expense of research, and the often limited life of new products, the pharmaceutical industry is more dependent on patents than any other. In the absence of foreign patents, competitors may obtain a free ride.

There is another special problem abroad. In many foreign countries, the patent laws have certain restrictive provisions with respect to pharmaceutical inventions. The basis is public policy, but the effect is actually discriminatory. I will come to various aspects of these restrictive provisions later. However at this point, I would urge the industry to take greater interest in the International Convention for Industrial Property. By discussion and exchange of views between the American association and the various foreign groups, there may be possibilities for revision and gradual relaxation of bars which would ultimately be reflected in the patent laws of the convention countries.

It is clear that the executives in charge of a pharmaceutical company's foreign policy have no easy task. Three principal reasons exist for obtaining foreign patents: (1) as assurance of a prima-facie right against others to import into the foreign country; (2) as a source of revenue from manufacturing licensees in the foreign country; and (3) as protection for manufacture by subsidiaries or affiliated companies. I believe there may be a fourth one: Salesmen abroad find the going smoother when backed up by patents. However, each of these reasons must be weighed against the hard alternative facts that any invention not patented in a foreign country can be used freely by foreign competitors and that all United States inventions obviously cannot be protected in all foreign countries if the company is to remain solvent. The only solution is to avoid arbitrary and empirical decisions, and to formulate a rational policy based on the nature and

potentialities of the company's products and a balancing of the efforts and expense involved against the profits accruing from foreign business.

Effects of Publication and Use

To implement a foreign patent program in an orderly manner, it is essential that those in charge of it should have a good working knowledge of some basic differences between United States and foreign patent laws and regulations and, in particular, the effects of publication and use of the invention. Foreign filing can be quite useless unless timed properly.

Inventors and clinical investigators in the pharmaceutical field are usually anxious to publish their results as soon as possible and sales managers are eager to ship new products to their distributors. But such publication and use may automatically destroy the possibility of securing valid foreign patents. There are many sad examples of rushing into print in haste, and repenting at leisure.

First and foremost, no publication or commercial use should take place before the United States patent application is filed; although harmless under the United States patent law for one year, this, in general, is not so in any other important country except Canada. Second, after the United States application has been filed, decisions concerning foreign filing, when to release publication and when to permit use must be made at appropriate times if full benefits are to be secured in the foreign field.

The international convention, which permits the benefit of the United States filing date to be claimed in a foreign country within one year, irrespective of any intervening publication or use, is of course a vast help—and most important countries are members of the international convention. This convention is one of the few international treaties which has survived two wars and is universally applauded as a sensible arrangement.

There is also the Buenos Aires Convention, having similar priority provisions, to which the United States and a number of Latin-American countries belong, and which is of use in those not belonging to the international convention. However, a few important countries, mostly in Latin America—such as Argentina and Chile—are entirely outside these mutually protective arrangements. It is true that some of these permit patents of confirmation, whereby a patent can be

obtained corresponding to an issued patent in another country, irrespective of any publication, provided there has been no use within the country. However, in view of the widespread international distribution of pharmaceuticals, it may not be safe to wait for a patent of confirmation.

The United States pharmaceutical manufacturer is almost always in a serious dilemma when considering foreign filing and balancing costs against potential advantages. It may take several years after the filing date of a United States patent application to test a new product. Should foreign filing be delayed until it is certain the product is valuable? Even if there is no publication or use, such delay may be dangerous, since—in view of competitive research—others may in the meantime have obtained dominating foreign patents. It is certainly safer to file within the priority year in convention countries and as promptly as possible in the nonconvention countries; once foreign filing has actually been effected, any subsequent publication and use can have no harmful effect.

A given situation must be judged on its merits; the important thing is to be aware of the essential foreign provisions, so that any failure to obtain foreign protection will be deliberate and not be an unwelcome surprise.

What to File and Where

What to file and where to file are, of course, fundamental considerations which may haunt the dreams of a company executive. An invention must obviously be evaluated in terms of its potential importance. If the invention relates to an improvement in a known process or a new product having only specialized uses, no foreign filing at all may be warranted, or filing only in a few selected countries where manufacturing licensees may be operating. But if no foreign patents are obtained on an important new product, such as a new antibiotic, it could be copied by competitors in numerous countries for both their own domestic markets and export to other consumer countries. Apart from the loss of revenue to the United States patentee, uncontrolled foreign competition can flood world markets with material of poor quality.

Fortunately, the procedure in most important foreign countries permits combination of a number of United States patent applications

into a single foreign application provided they all generally relate to the same invention. Here, an important new development is usually protected in a series of United States patent applications as research develops. Very often these can be sewn together into a single foreign application in the name of the assignee company (even though the United States inventors may be different). Since convention priority dates are so important in these competitive days, it is highly desirable that important new developments should be filed in the United States Patent Office within a year from the first filing. Combination can then be effected with the benefit of multiple convention priorities. However, United States applications more than a year apart can often be combined either without priority or with partial priority.

Also, most foreign countries permit later improvements to be protected as patents of addition to earlier patents. These are not subject to maintenance taxes—a topic mentioned later.

Four other factors must also be considered in selecting individual countries and determining the use and value of foreign patents: (1) the type of protection possible—whether product and/or process claims are obtainable, (2) whether patents will prevent importation of products, (3) the working and compulsory licensing provisions in foreign patent laws and (4) the expense of foreign taxes.

Product and Process Claims

The United States patent system permits independent product claims for new pharmaceutical products, not limited to the process of manufacture. Apart from a few notable exceptions, this is not the case at the present time in numerous foreign countries, where the nature of the patent protection granted to pharmaceutical inventions is the subject of much debate and reappraisal. Extremely conflicting viewpoints have not yet been resolved as regards the basic problem—are the interests of the public best served by a broad monopoly in the product or by a limited monopoly restricted to the product as made by the process actually disclosed?

There is a considerable amount of history involved in this situation, and it is probably simpler to start in the middle and review European ideas, particularly in the highly industrialized countries.

The limitation of protection for chemical products in general, as well as pharmaceutical products in particular, to process claims is

essentially a continental European conception and is tied up with social thinking in the nineteenth century during the industrial revolution. It became a matter of practically unassailable dogma that if the public was to receive the benefit of new chemical or pharmaceutical products at reasonable prices and in amounts sufficient to meet the demand, this could be accomplished only by restricting the inventor to his process so that others would be encouraged to invent new and improved processes which would make the product cheaper and available in greater quantity. Probably there was also the fear that, with so many closely adjacent countries, product claims would enable the manufacturer in one country to obtain effective control of the entire European market. These European ideas regarding the desirability of process limitation for pharamceutical inventions were transplanted many years ago to numerous other regions and particularly to certain Latin-American and Far Eastern countries.

The British viewpoint of the nineteenth century was different, and product claims were then permitted. However, the process limitation was introduced in 1919, largely as a result of numerous broad product claims for dyestuffs obtained by German inventors before World War I and the fear of domination of the British industry by German interests. Some of the major British colonies followed suit; some did not. After 30 years, there has now been another about-face. In the new 1949 British Patent Act, independent product claims are again permitted.

This somewhat unexpected, but logical, change in British practice has had a profound effect in foreign patent circles. In many countries now permitting only process claims, the desirability of independent product claims in patents for new pharmaceutical products is being most carefully considered as to whether, in view of present conditions and the enormous expansion of the chemical and pharmaceutical industries, limitation to process protection may be outmoded and actually harmful. The number of new compounds that can be created is so great, the spur of competition is so strong and the cost of research is so large that no manufacturer rests on his oars after placing a new product on the market; he will himself continue to work on improved methods of production. From the viewpoint of the public interest and the commercial utilization of a new product, all the novelty and advantages actually reside in the product itself, and it is immaterial whether the product is produced by an entirely

new reaction or by a conventional reaction. If the reaction process itself is new, this in turn promotes research to utilize it in the production of other new products. It can be argued vigorously that, in countries in which patent-office practice holds that utilization of a known process to produce a new product is obvious, research is actually stifled. The public benefits from the product and not from the process.

However, as a practical matter, at the present time, the list of important countries where independent claims are granted for pharmaceutical products is very small—namely, Australia, Belgium, Cuba, Great Britain, Israel, New Zealand, the Philippines and Union of South Africa. In addition, there are a few minor countries in Latin America, and those British colonies where British patents can be registered.

Since process claims are, therefore, the chief mode of protection in foreign pharmaceutical patents, it is important that United States patent applications which may later be filed abroad should be prepared with the foreign requirements in mind—that is, a full disclosure of the method even though only the product is claimed.

Importation of Products

A very important related question for United States pharmaceutical manufacturers is: Do foreign pharmaceutical patents prohibit importation of the product? It can be stated categorically that in Europe and in practically all important countries outside Latin America, they do and, in general, process claims are regarded as inherently including the immediate product thereof. The burden of proof as to whether the product is actually made by the claimed process is generally either on the infringer or the patentee, depending on whether the product is new or old. However, in a large number of countries in Latin America, it is considered that process claims do not cover the product, and since product claims are not permitted in most of them, it follows that process claims cannot be used to stop importation of the product.

In the absence of decisive patent litigation in these countries, to some extent this is a matter of opinion and, consequently, there is a strong tendency to settle important disputes by negotiation.

Working and Compulsory Licensing

The patent laws of practically all the major foreign countries state that an invention should be worked, usually, within three years from the date of grant. By "working" is meant carrying out the invention defined in the claims of the patent, within the foreign country, to an extent sufficient to meet the full requirements of the public at a reasonable price—that is, in the case of a pharmaceutical product, it should be manufactured within the country and not be imported. The foreign working provisions constitute a further great distinction between United States and foreign practice. The theory is that an unused monopoly is not in the public interest and, in effect, hangs like a club over industry for the life of the patent and hinders further development. This, of course, is a debatable proposition. However, as a practical matter, the penalty for nonworking is not too serious. In a few relatively minor countries, a patent may actually be subjected to attack by third parties or invalidated by the patent office or courts for nonworking, but in the important convention countries, the preferred remedy for nonworking is "compulsory licensing." This term has been widely misunderstood and to a considerable extent is not as compulsory as it sounds. Very few compulsory licenses are actually granted in convention countries for patents in most fields, though the situation is somewhat stricter for pharmaceutical inventions. To obtain a compulsory license, a third party must file a petition to establish that he is able to supply the public demand at a reasonable price by manufacture within the country. The patent office, after full consideration of all the facts, including objections by the patentee, has discretion to determine whether or not a compulsory license should be granted and, if so, what royalties should be awarded to the patentee. In actual practice, a potential licensee usually approaches the patentee for a voluntary license. It is only in the event that an amicable settlement cannot be reached that compulsory license proceedings are begun. The normal period for working for most countries begins three years from the date of grant of the patent. However, in England and in a number of British dominions and possessions, where a pharmaceutical invention is involved, a third party can petition for a license as soon as the patent is granted.

The rule of reason also applies to compulsory licensing. If a pharmaceutical product is not successful, no one is likely to ask for a license. However, if the product is of major importance, the United

States owner of foreign patents must be prepared to face the fact that if he does not manufacture abroad, he may have to share the market with foreign manufacturers, subject to royalty payments.

Taxes on Foreign Patents

Unfortunately, most foreign countries demand taxes at various times usually every year and usually graduating upwards with the age of the patent, to maintain a patent in force. This is not the place to consider the merits or demerits of such taxes. They exist and they must be paid. But, also, they are extremely variable from country to country. Therefore, to avoid service charges on individual payments, in certain countries prepayment of taxes in a lump sum—if permitted—may be advisable. This will obviously depend on the amount of the taxes and the estimated future importance of the invention.

The subject is more or less empirical. Certain cautious rules can be worked out for certain countries for the early years of a patent, unless a pioneer invention is recognized at the start so that complete or substantial prepayment of taxes may be justified. However, in general, it should be the duty of the patent committee of a pharmaceutical company to evaluate the commercial worth of foreign patents each year in relation to the cost of maintenance.

Selection of Countries

At this point, in the light of the above discussion, it would appear that the following main factors should be considered when selecting foreign countries in which to obtain patents for pharmaceutical inventions:

(1) The nature and potential importance of the invention and whether, in the absence of foreign patents, copying would be a temptation for competitors.

(2) Whether product or process claims could be obtained in a given country, whether such claims would be broad or limited and whether they would provide protection against importation.

(3) Whether the nature of the invention is such that it would be used only in a few countries or whether it would have a potential market throughout the world.

(4) Whether the foreign patents would be used by existing or prospective licensees or affiliates, or would be intended primarily to

protect export markets—bearing in mind the attitude toward pharmaceutical patents in the particular country and also the ultimate possibility that others might apply for compulsory licenses in the absence of domestic manufacture.

What Can Be Protected

Without going into any details of practice, it may be of interest to review very briefly what can be protected in a foreign pharmaceutical patent and to consider the special problems of mixtures and antibiotics.

The simplest type of pharmaceutical invention to claim is a single specific new compound. This can be fully defined verbally or by formula, and its preparation can be clearly exemplified. However, such cases are somewhat rare. More usually, a new series of compounds is produced having a class formula. Whether or not a particular country permits product claims or only process claims, the problem is to define the range of variables in the class formula. If there are substituents, such as alkyl or aryl groups, the number of carbon atoms or some other appropriate identification for the beginning and end of the range should be given, and specific examples should illustrate compounds throughout the range. In a well-known leading case in England, a general formula was proved to cover some millions of possible compounds, whereas only two compounds were specifically described. The British courts held the claims were "covetous" and the patent was declared invalid.

In some countries, a new series of compounds is considered as a chemical invention with the pharmaceutical properties incidental. However, most countries require the pharmaceutical properties to be given in some detail, which is difficult at the early stage of development, in view of the time necessary for satisfactory clinical tests. Therefore, from the viewpoint of validity and obtaining strong pharmaceutical patents, it is probably better to limit the claims to new compounds for which the beneficial pharmaceutical properties have been positively demonstrated. If new compounds in a series are later found to have similar properties, these can usually be protected in patents of addition.

The protection of mixtures, as distinguished from products of a chemical reaction, is difficult, to say the least—that is, where known

ingredients having pharmaceutical properties are mixed with other known ingredients which in themselves may be pharmaceuticals or carriers or extenders. Should the public be prevented from buying and mixing ordinary and well-known compounds? If not, what can be regarded as patentable in a mixture? What is not patentable is probably best expressed in the British patent law as follows:

> If it appears to the comptroller in the case of any application for a patent that it claims as an invention a substance capable of being used as food or medicine which is a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients, or that it claims as an invention the process producing such a substance by mere mixture, he may refuse the application.

In general, all the important countries having a strict examination use this criterion, some more stringently that others. An unexpected effect, beyond the aggregate of the known properties, requires synergism, involving some form of interaction of the ingredients in the mixture as distinguished from ordinary chemical reaction. The synergistic effects may be of widely different types—unexpected preservative or antiseptic properties, reduction of toxic effects, etc. There is probably a general tightening up in most patent offices in regard to mixtures; because some synergism between active compounds is more or less normal, examiners are looking for exceptional or unexpected synergism.

The protection of antibiotics constitutes a new and specialized branch of patent practice. In general, all basic antibiotic patents are similar in form, and inherently involve fermenting a specified organism in a nutrient medium. This sounds straightforward enough. Actually, it is not, and patent practice is becoming involved in semantics. In the first place, it is very rare that the identifying structural formula for a new antibiotic can be worked out by the time a patent application is ready to be filed; therefore the product is defined by name, which is nothing more than saying it is the product of fermenting the specified organism. The novelty then resides in discovering and using an organism, since fermentation techniques in themselves are old and conventional. Invention defined as discovery involves treading on dangerous ground. It is probable that patents in countries permitting product claims are stronger than in those having only process claims. The products can usually be defined precisely by their infrared spectra, although, in a few countries, examiners have tentatively proposed that antibiotics are actually natural products and may be found in nature in an appropriate environment. The situation is further complicated by the fact that the organisms themselves seem to be becoming elusive as

generations multiply, and susceptible to very wide variations in morphological characteristics.

Until now, basic antibiotic patents have been granted in very broad form in most countries throughout the world. But patent office examiners are becoming wary, and litigation has begun. Where the same antibiotic is produced by allegedly different organisms, the courts are likely to be faced with an almost insuperable task. There are few experts competent to lead a judge through the jungles of morphological data. A most interesting theory has recently been proposed in Germany—that when a later patent produces the same antibiotic as an earlier patent using an allegedly different organism, this is merely an analogy process involving no new technical effect and, therefore, not patentable. This would by-pass comparison of the organisms.

Future Picture

To look into the future, a crystal ball is not required—assuming no more world wars. The world population curve is rising, and public health is of growing concern in what we consider the less-developed and overpopulated countries. Therefore, clearly, there will be increasing consumption of pharmaceutical products abroad. From the viewpoint of the industry in the United States, there may be stronger emphasis on Latin America, Africa and the East. However, in many countries in these regions patents are granted without examination or with superficial examination. They are more or less naked rights with strong teeth in them, but possibly vulnerable with respect to compulsory licensing and special regulations relating to importing. Difficult as it may prove in practice, the future maintenance of satisfactory foreign patent positions is likely to depend more and more on cooperation with expanding local industry. **[The End]**

• ANTITRUST REPORTS ARE ISSUED •

A staff report entitled *Corporate Mergers and Acquisitions* has been released by the Senate Subcommittee on Antitrust and Monopoly, for the information of the members of the Committee on the Judiciary (Senate Report No. 132, Eighty-fifth Congress, First Session). The report is in the nature of a research study.

The activities of the Senate subcommittee during 1956 and a staff study of the view of the federal judiciary on the efficacy of the antitrust laws are the subjects of another report of the Senate committee. The report, *Antitrust and Monopoly*, is Senate Report No. 128, Eighty-fifth Congress, First Session.

CHRISTOPHER

COMMENTS

Thomas W. Christopher is associate dean and professor of law at Emory University, Atlanta, Georgia.

Privity.—An Ohio court has issued an illuminating decision dealing with the necessity for privity in warranty and implied-warranty actions.[1] Involved was a cosmetic bought at retail by a user, the suit being against the manufacturer. The manufacturer had made representations in his advertising which had induced the consumer to buy the product.

The court held: (1) Privity is not necessary (in an *express-warranty* count) where the express representations made by the manufacturer in advertisements induced the consumer to buy. (2) Privity is necessary in a count for breach of *implied warranty* of fitness or merchantability.

On the first holding, the court wrote:

> Where a manufacturer induces the purchase of his products by an ultimate consumer by representations as to their quality, purposes and uses, which are relied on by the purchaser, and where such representations are untrue so that the purchaser is damaged in using the product for the purpose as advertised, the common law theory of express warranty should be available to the purchaser regardless of privity.

As to the second holding, the court reluctantly held that privity was necessary, due to prior decisions of the court.

It is a full and able decision, and is recommended reading for lawyers in the field.

Alcoholic-Beverage Industry and the Sherman Act.—A recent decision held that the Sherman Antitrust Act applies to the liquor industry. The Twenty-first Amendment to the federal Constitution provides that the commerce powers of the federal government, as to liquor, are subordinate to state powers. Based on this, the defendant con-

[1] *Rogers v. Toni Home Permanent Company*, CCH Food Drug Cosmetic Law Reports ¶ 22,471 (Ct. of App., Ohio, 1957).

tended that the Sherman Act does not apply to liquor which has come to rest in a state. The court held that the Act applies, at least so long as there is no conflict with state statutes.[2]

This is an interesting issue, due to the fact that here is one of the few instances where state power is superior to federal commerce power.

FOODS, DRUGS—BROKERAGE FEES, PROMOTIONAL ALLOWANCES, PRICE DISCRIMINATION, MISREPRESENTATION

Food products . . . A food broker would be prohibited from "splitting" commissions with buyers. Specifically, a company placed an order for apple concentrate, offering to pay $1.25 a gallon. The seller would not sell for less than $1.30. The sale was made, however, when the broker allegedly accepted from the seller a fee of 4 per cent instead of the usual 5 per cent. (Released March 8, 1957.)

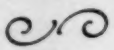
A wholesale distributor of food products is charged with receiving brokers' fees on the products it purchases for its own account. (Issued February 21, 1957; released March 4, 1957.)

A manufacturer of jellies and preserves is charged with receiving brokerage on the foodstuffs it buys, in violation of the Robinson-Patman Act. (Issued February 18, 1957; released March 1, 1957.)

A complaint charging a food-products company with discriminating among its customers by failing to offer its regular cooperative advertising program to all its customers and by giving special allowances to a chain store would be dismissed for lack of evidence. (Released March 9, 1957.)

Milk . . . A milk company is charged with selling milk to its Delaware customers at prices substantially lower than those charged customers in Pennsylvania and New Jersey and with giving favored customers cash-purchase discounts. (Issued March 8, 1957; released March 15, 1957.)

Vitamin capsules . . . A firm is charged with advertising a deceptive "30-day free trial" offer in order to sell its vitamin capsules. (Issued March 6, 1957; released March 13, 1957.)—CCH TRADE REGULATION REPORTS ¶ 26,409; 26,392; 26,387; 26,403; 26,412; 26,407.



[2] *U. S. v. Erie County Malt Beverage Distributors Association*, CCH Trade Regulation Reports ¶ 68,590 (DC Pa., 1957).

STATE

FOOD AND DRUG NOTES

For the March issue of the *JOURNAL*, we devote this department to a brief history of the main laws supervised by the food and drug commissioner of the State of Nevada. E. L. Randall, who has written this interesting contribution, was appointed commissioner and state sealer in 1954.

NEVADA first prohibited the adulteration of foods and drugs by legislative act in 1909. The law became effective January 1, 1910. Its administration was placed under the Department of Agriculture, on the campus of the University of Nevada in Reno.

S. C. Dinsmore, a graduate of the University of Maine, was appointed commissioner, and started enforcement of the law on the effective date. He was ably assisted by Miles B. Kennedy, who still lives in Reno in retirement, and S. E. Ross, who was teaching agricultural chemistry at that time and who recently retired as chairman of the board of regents of the University of Nevada. Both of these men served as chemists and inspectors in the early years of the department. A few years later, Percy Nash was appointed resident inspector in Las Vegas.

The original law contemplated two objectives: (1) the proper branding and labeling of food and drug products and (2) the elimination of all articles detrimental or injurious to health. In 1913, the legislature rewrote the law to include a provision for sanitary inspection of all places where food products were manufactured, stored, or offered for sale. This same legislative session appropriated $12,000 to run the food and drug department for a period of two years.

In 1911, the weights and measures law was enacted and was placed under the supervision of the food and drug commissioner. Shortly thereafter, the departments were placed in the public-service division

of the university, with the commissioner being appointed by the board of regents. The departments were located at Fifth and Sierra Streets in Reno. They still function from this location, under the university. A branch office has been opened in the new state building in Las Vegas, and we are presently making legislative plans to open another branch in Elko to cover the eastern part of the state.

In 1931, the petroleum products inspection act was added to the responsibility of the weights and measures department.

In 1939, the food and drug law was again rewritten to follow the model state law and the new federal law passed in 1938. The law was extended to cover cosmetics and devices at this time. A few years later, in 1942, Mr. Dinsmore died, and was succeeded by Wayne B. Adams, who had been a chemist in the department since his graduation from the University of Nevada in 1917. The antifreeze act was passed in 1949, during Mr. Adams' administration as commissioner and state sealer. He passed away in 1954, after 34 years of intensely active and devoted service to food-and-drug and weights-and-measures work.

Today, there are actually three divisions in our department: (1) food and drug, cosmetics and devices, (2) weights and measures and (3) petroleum products inspection, with a staff of 11 full-time members —the commissioner and state sealer; two chemists; six inspectors; and two secretaries.

Our food and drug department today is still waging a vigorous enforcement program to carry out the aims of the original law. Amendments and regulations are frequently added to meet the problems created as a by-product of the rapid advances in food technology and in the drug industry.

M. H. GORDON APPOINTED TO VA LABORATORY POST

Appointment of M. H. Gordon, Ph. D., as assistant director of the central research laboratory for the nation-wide evaluation of tranquilizing drugs in Veterans Administration hospitals was announced by VA on February 21. Formerly chief of the clinical psychology service at the administration's hospital in Knoxville, Iowa, Dr. Gordon now works at the VA hospital at Perry Point, Maryland, base for the new tranquilizers study.

Dr. Gordon, since 1947, had served as a clinical psychologist—at the administration's general medical and surgical hospital in Memphis, Tennessee; at the Chillicothe, Ohio VA hospital; and at Knoxville.

CANADA-

FOOD AND DRUG ITEMS

A trade information letter has been received from the Canadian Department of National Health and Welfare. It reads, in part, as follows:

January 18, 1957—No. 146.—

"To: *Manufacturers of Agricultural Chemicals and Agriculturists*

"Re: *Tolerances for Residues of Agricultural Chemicals.*

"Residue tolerances of agricultural chemicals and more particularly the pesticides are being established for food crops grown in Canada or grown elsewhere and imported into Canada.

"The rate of application and the time of application of the agricultural chemical should be so regulated that the established residue tolerance is not exceeded. Persons selling food with a residue of a substance indicated below with a residue in excess of the levels shown may be subject to the penalties of the Food and Drugs Act for a violation of Section 4(a) of the Act.

"Subsequent to Trade Information Letter No. 137 issued in June 1956 the following residue tolerances have now been established and are listed in Section B. 15.002 of the Food and Drug Regulations as amended.

". . . [At this point, the schedule of tolerances is reproduced.]

"Any food having in or upon it at the time of sale, an agricultural chemical for which a residue tolerance has not been established in the regulations as promulgated in the Canada Gazette is in violation of the Food and Drugs Act. Unless a residue tolerance has been established on a particular crop none of these above substances should be present in or upon the food. In order to facilitate the preparation of spray calendars for the 1957 growing season it has been deemed reasonable to request that all submissions for materials likely to be needed should be made before April 30, 1957.

"Generally, a herbicide applied prior to sprouting or as a pre-emergence spray, will contribute no residue to the edible crop. If however, residues are present on the edible portion of the crop at the time of harvest or of sale, then a submission will be required.

"Residue tolerances for agricultural chemicals may be established on request for such chemicals deemed to be useful and effective for the purpose recommended, provided satisfactory data as to safety of use and other information is supplied to the Director of the Food and Drug Directorate of the Department of National Health and Welfare in accordance with Trade Information Letter No. 124.

"The establishment of a tolerance requires an amendment to the Food and Drug Regulations. Orders-in-Council amending the Regulations are published in Part II of the Canada Gazette.

". . . [signature]
C. A. Morrell,
DIRECTOR,
FOOD and DRUG DIRECTORATE."

REPORTS TO THE READER—Continued from page 132

"Do these materials occur in the food supply of the United States? Arsenic is the only one. It may occur in some foods in extremely small concentrations as a pesticide residue and is normally present in certain foodstuffs which have received no pesticide treatment. Insofar as is known, there is no danger from the amount of arsenic likely to be consumed from these sources under ordinary conditions.

"If this were all of the story, probably no public apprehension would have arisen.

"Cancer in experimental animals versus cancer in the human

"Investigators studying cancer have induced the development of tumors in experimental animals by purposely exposing them to a number and variety of chemicals. Such experimental cancer may be produced in animals by giving the agent by injection, by skin application, or orally. From this evidence and knowledge of how man may be like or different from the experimental animal in the metabolism, excretion, or storage of a particular chemical, the scientist can form a hypothesis as to how man might react to the ingestion of the chemical. In this respect, the conservative position would demand that substances that produce cancer in experimental animals should be excluded from human foods as a precautionary measure, even though it is known that a substance carcinogenic in one species is not necessarily carcinogenic in others.

"Knowledge about possible cancer-causing agents in foods is, in general, at the point that studies are being devised and undertaken to test such possible relationships. This research is, by its very nature, expensive and time consuming. Years of study will be required to build definitive knowledge concerning all causes of cancer. There is a need to continue and expand present efforts to identify any relationships which may exist between environmental factors and the occurrence of cancer in man. Measures taken to safeguard the food supply can be only as effective as our state of knowledge permits. Government agencies, the food industry, and bodies such as the National Research Council are working together to facilitate the development of this knowledge and its effective application as soon as the information becomes available."

Pharmaceutical Colleges Endorse *Journal*

Raymond J. Dauphinais, assistant professor at the University of Connecticut School of Pharmacy and former Food Law Institute fellow at New York University School of Law, forwarded to us the following statement:

"Did you know that the JOURNAL was one of the titles included in a recent list of periodical literature recommended for college of pharmacy libraries? The JOURNAL was included as a result of pooled opinions of the teaching staffs and all the librarians in accredited colleges of pharmacy. The report was by the Medical Library Association Committee on Standards and Criteria for Pharmacy School Libraries, and was reprinted in the *American Journal of Pharmaceutical Education.*"

We are honored to be included in the committee's important list, and thank Mr. Dauphinais for bringing this fact to the attention of FOOD DRUG COSMETIC LAW JOURNAL and its readers.

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